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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF OHIO

EASTERN DIVISION

- - -

IN RE: NATIONAL : MDL NO. 2804

PRESCRIPTION OPIATE:

LITIGATION

\_\_\_\_\_

: CASE NO.

THIS DOCUMENT : 1:17-MD-2804

RELATES TO ALL CASES:

: Hon. Dan A.

: Polster

Tuesday, January 15, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped deposition of LINDA KITLINSKI, taken pursuant to notice, was held at Golkow Litigation Services, One Liberty Place, 1650 Market Street, Suite 5150, Philadelphia, Pennsylvania 19103, beginning at 9:05 a.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter.

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GOLKOW LITIGATION SERVICES 877.370.3377 ph | 917.591.5672 fax deps@golkow.com

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      APPEARANCES:
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                                                                                APPEARANCES: (Continued)
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                                                                                Jobina Jones-McDonnell, Endo Pharmaceuticals
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          John cella@arnoldporter com
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22
                                                                       22
          Endo Pharmaceuticals, Endo Health,
                                                                       23
23
          and Par Pharmaceuticals
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24
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       APPEARANCES: (Continued)
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           PIETRAGALLO GORDON ALFANO BOSICK &
           RASPANTI, LLP
                                                                             Testimony of: LINDA KITLINSKI
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           BY: ASHLÉY KENNY, ESQUIRE
           1818 Market Street
                                                                                By Ms Aminolroava
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           Suite 3402
                                                                                By Mr Buchanan
                                                                        6
           Philadelphia, Pennsylvania 19103
                                                                                By Mr Davis
 6
           (215) 320-6200
           Representing the Defendant,
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           Cardinal Health, Inc.
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           JONES DAY
           BY: TAYLOR A. GOODSPEED, ESQUIRE
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           555 California Street
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           26th Floor
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           San Francisco, California 94104
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           (415) 626-3939
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           Tgoodspeed@jonesday.com
           Representing the Defendant,
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           Walmart
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       VIA TELEPHONE/LIVESTREAM:
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Exhibit-3 ENDO-OPIOID_MDL-02344002,
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           REED SMITH, LLP
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           BY: MOLLY Q. CAMPBELL, ESQUIRE
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           1301 K Street, N.W.
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           Suite 1000 - East Tower
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           Washington, D.C., 20005
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           Mqcampbell@reedsmith.com
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           Representing the Defendant,
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           AmerisourceBergen Drug Corporation
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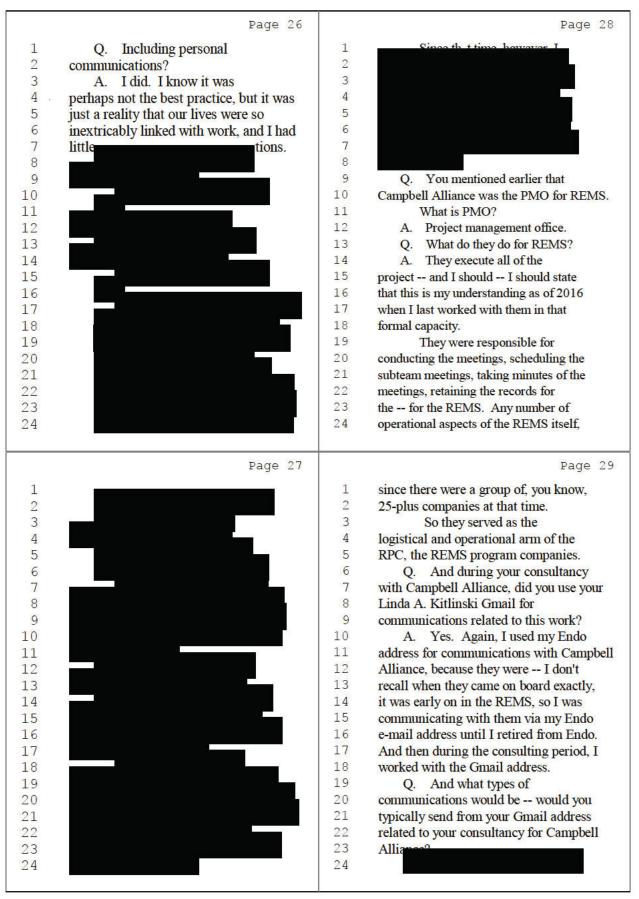
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            2003-2012
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            329
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      Endo-Kitlinski
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19
             Quality
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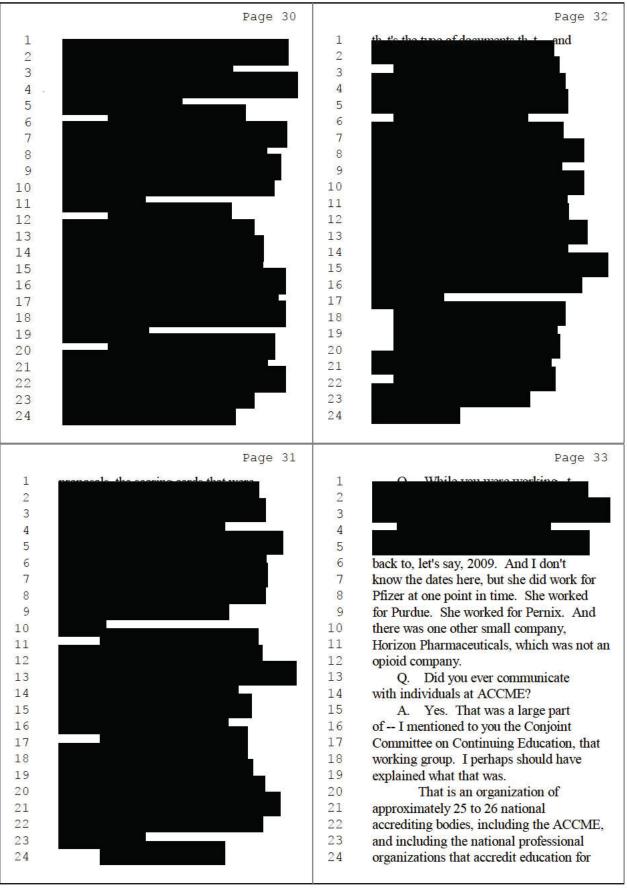
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1 2	EXHIBITS	1 2		
3	3		(It is hereby stipulated and	
5			agreed by and among counsel that	
6	Exhibit-46 ENDO-OPIOID_MDL_DEPONENT- 6 000015904-16398 379		sealing, filing and certification	
7	Endo-Kitlinski	5	are waived; and that all	
8	Exhibit-47 Hard drive 421		objections, except as to the form	
	Endo-Kitlinski		of the question, will be reserved	
9	Exhibit-48 ENDO-OPIOID_MDL-04908487- 488, with attachment 426		until the time of trial.)	
10	,			
11	Endo-Kitlinski Exhibit-49 No Bates	10	VIDEO TECHNICIAN: We're now	
12	Amended Subpoena to Testify	11	on the record. My name is David	
12	At a Deposition in a Civil Action 432	12	Lane, the videographer for Golkow	
13	Endo Vitlindi	13	Litigation Services. Today's date	
14	Endo-Kitlinski Exhibit-50 ENDO-OPIOID_MDL-01769386-	14	is January 15th, 2019. Our time	
15	592 495	15	is 9:05 a m.	
	Endo-Kitlinski	16	This deposition is taking	
16	Exhibit-51 ENDO-OPIOID_MDL-02343835, With attachment 594	17	place in Philadelphia,	
17		18	Pennsylvania, in the matter of	
18	Endo-Kitlinski Exhibit-52 ENDO-OPIOID_MDL_DEPONENT	19	National Prescription Opiate	
	000000184-189 617	20	Litigation, MDL. The deponent	
19 20		21	today is Linda Kitlinski. Our	
21 22		22	counsel will be noted on the	
23		23	stenographic record. Our court	
24		24	reporter today is Amanda Miller	
			Page 13	
	rage II			
1		1	and will now swear in the witness.	
2	DEPOSITION SUPPORT INDEX	2		
3		3	LINDA KITLINSKI, after	
4		4	having been duly sworn, was	
5	Direction to Witness Not to Answer	5	examined and testified as follows:	
6	Page Line Page Line Page Line	6		
7	284 11	7	VIDEO TECHNICIAN: Please	
8		8	begin.	
9	D	9		
10	Request for Production of Documents	10	EXAMINATION	
11	Page Line Page Line Page Line	11		
12	None	12	BY MS. AMINOLROAYA:	
13		13	Q. Good morning, Ms. Kitlinski.	
14	Cr. 1 ··	14	We met a few moments ago off the record.	
15	Stipulations	15	My name is Parvin Aminolroaya, and I	
16	Page Line Page Line Page Line	16	represent some of the plaintiffs in the	
17	12 1	17	opioid litigation.	
18		18	Would you please state your	
19	O - C - M-1 - 1	19	name for the record?	
20	Question Marked	20	A. Linda Ann Kitlinski.	
21	Page Line Page Line Page Line	21	Q. And have you ever been	
22	None	22	deposed before, Ms. Kitlinski?	
23		23	A. No, I have not.	
24		24	Q. So I'm just going to go over	
		1		

Page 14 Page 16 1 1 a few ground rules. Your counsel may A. No. 2 have gone over them, but I want to make 2 VIDEO TECHNICIAN: Going off 3 sure we're on the same page. 3 the record. 9:08 a m. 4 4 If you don't understand a 5 5 question, please tell me. And I will be (Whereupon, a brief recess 6 6 asking a lot of questions throughout the was taken.) 7 day, there may be times when I don't 7 8 succeed in asking a question that you 8 VIDEO TECHNICIAN: We're 9 9 understand. Just let me know. back on record at 9:10 a.m. 10 10 Otherwise, the record will reflect that BY MS. AMINOLROAYA: 11 11 the question was understood. Q. We just took a short break I'll ask you to answer with to handle a small technical issue. We're 12 12 13 a verbal yes or no. Please don't nod or 13 back on the record. 14 shake your head. The court reporter 14 Ms. Kitlinski, what did you should be able to take down what we're 15 do to prepare for your testimony today? 15 A. I read the subpoena 16 16 saying. 17 documents thoroughly. I went through my 17 And in the course of normal 18 files, gathered up the requisite 18 conversation, sometimes you can 19 materials that were referenced in there, 19 anticipate what I'm saying so you may 20 provided those to counsel. Met with 20 know the answer before I even finish the 21 question. But for purposes of having a 21 counsel on three occasions for a few 2.2 clean record, please wait until I finish 22 hours. And I'm here today. 23 23 my question before giving your answer. Q. And when did you first 24 And I'll remind you of that if it seems 24 receive a subpoena? Page 17 Page 15 like we're talking over each other during 1 A. I'm going to say it was in 1 2 2 October. That's a guess. It was prior the deposition. 3 We can take a break whenever 3 to the first week of November, I know that, but I don't know the exact date. 4 you need, just let me know. The only 4 5 5 thing I would ask is that if there's a Q. And what did you do to 6 question pending, you answer the 6 undertake the thorough search you just 7 described in response to the subpoena? 7 question. 8 8 A. Well, I went through my Do you understand these 9 9 personal -- first of all, the documents instructions? 10 10 that I had in my possession were A. Yes, I do. subsequent to my employment from Endo. I Q. And do you understand that 11 11 12 you're under oath as if you were in a 12 had turned everything in, you know, when 13 I retired, or during subsequent -- I 13 court of law before Judge Polster in 14 Ohio? 14 mean, during the orders that they had in A. Yes, I do. 15 place prior to that time. 15 16 So I went through my 16 Q. And if you don't know an 17 materials. And I extracted anything that 17 answer to a question or can't recall, 18 had anything to do with opioids or the 18 just let me know. But please don't 19 other criteria that were listed in the guess. However, we are entitled to your 19 20 20 best recollection. subpoena. 21 21 Is there anything we should I did a key word search, and 22 know that would prevent you from 22 I have on my -- on my computer the -- any of the documents that -- as well as on my 2.3 testifying truthfully and to the best of 23 24 laptop, on my thumb drive, I have one 24 your ability today?

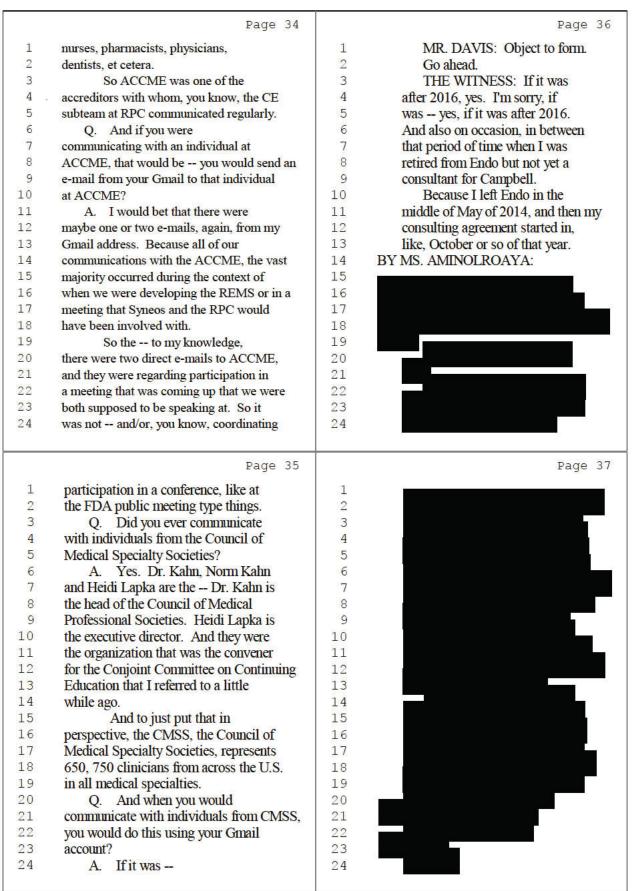
thumb drive that I have used since leaving Endo, and that's where I have looked for those documents.  Q. What search terms did you use?  A. Anything related to opioids, you know they were listed in your document there, opioids, oxymorphone, Opana, REMS.  Q. And where on your computer did you search?  A. I searched my in my folders. And I searched the thumb drive that Use. I also searched the thumb drive that Use. I also searched the fumb drive that Use. I also searched the fumb drive that Use. I my in my folders. And I searched the fumb drive that Use. I my in my folders. And I searched the fumb drive that Use. I my in my folders. And I searched the fumb drive that Use. I my in my folders. And I searched the fumb drive that Use. I my in things not related to this case, you know, people soliciting your papticipation in things not related to this case, you know, just regular, everyday coupons and that type of thing. The other e-mails in my file were copied to the folks at the REMS, again, they are also copied on the Syncos finVentiv documents since they re in attendance at that meeting and take minutes.  Page 19  A. Between the time I received the subpoena and this case, retained those family documents.  A. Yes.  Q. And you applied the search terms that were identified in plaintiffs' subpoena?  A. Yes.  Q. And upou turned those documents over to your counsel?  A. Yes.  Q. And turning to your e-mails—  A. Excuse me, just to clarify, you searched the thumb drive pouncants, which came from my files, over to counsel. And I turned the thumb drive that did not have my family information to the my formation related to the—to this case.  Q. And what kinds of documents  Teage 19  A. Page 21  were on the thumb drive?  A. Oh, they were things like the minutes from the FEMS.  A. Anytes.  Q. And what kinds of documents  They would circulate the minutes for committee members who participate in the search term in the search term in the search terms that they reflected accurately what people who participated						
leaving Endo, and that's where I have   2   looked for those documents.   3   documents.   4   Q. What search terms did you use?   5   Sarah (acument there, opioids, soymorphone, 9   Opana, REMS.   9		Page 18		Page 20		
leaving Endo, and that's where I have looked for those documents.   2	1	thumb drive that I have used since	1	that was not related to the subpoena and		
looked for those documents.	2	leaving Endo, and that's where I have	2	this case, retained those family		
searched the fumb drive?  A. Anything related to opioids, you know they were listed in your document there, opioids, oxymorphone, Opana, REMS.  D. A. Anything related to opioids, oxymorphone, Opana, REMS.  A. Anything related to opioids, oxymorphone, Opana, REMS.  D. A. Anything related to opioids, oxymorphone, Opana, REMS.  D. A. Anything related to your documents were in your computer did you search?  A. Yes.  Q. And you applied the search terms that were identified in plaintiffs' subpocona?  A. Yes.  Q. And you turned those documents over to your counsel?  A. Yes.  Q. And turning to your counsel?  A. Yes.  Q. And turning to your enails - termish and terms that were identified in plaintiffs' subpocona?  A. Yes.  Q. And turning to your enails - termish you.  A. I turned some paper documents, which came from my files, over documents who participate in the REMS, again, they are also copied on the Symposis/ metric documents since they're in attendance at that meeting and take minutes.  Q. And when did you run the search in your e-mail?  A. Yes.  Q. And turning to your e-mails - termish at were identified in plaintiffs' subpocona?  A. Yes.  Q. And turning to your e-mails - termish at were ocounsel. All turned the thumb drive that did not have my family information but had the information related to the - to this case.  Q. And what kinds of documents to this case.  Q. And what kinds of documents  They would circulate the minutes from the from the REMS meetings, the agenda, the participants.  They would circulate the minutes for comments to make sure that they reflected heard.  A. Yes.  Q. And turning to your e-mails - termish at were open documents with add the information related to the - to this case.  Q. And what kinds of documents to counsel. All turned the thumb drive?  A. Oh, they were things like	3		3			
searched the fumb drive?  A. Anything related to opioids, you know they were listed in your document there, opioids, oxymorphone, Opana, REMS.  D. A. Anything related to opioids, oxymorphone, Opana, REMS.  A. Anything related to opioids, oxymorphone, Opana, REMS.  D. A. Anything related to opioids, oxymorphone, Opana, REMS.  D. A. Anything related to your documents were in your computer did you search?  A. Yes.  Q. And you applied the search terms that were identified in plaintiffs' subpocona?  A. Yes.  Q. And you turned those documents over to your counsel?  A. Yes.  Q. And turning to your counsel?  A. Yes.  Q. And turning to your enails - termish and terms that were identified in plaintiffs' subpocona?  A. Yes.  Q. And turning to your enails - termish you.  A. I turned some paper documents, which came from my files, over documents who participate in the REMS, again, they are also copied on the Symposis/ metric documents since they're in attendance at that meeting and take minutes.  Q. And when did you run the search in your e-mail?  A. Yes.  Q. And turning to your e-mails - termish at were identified in plaintiffs' subpocona?  A. Yes.  Q. And turning to your e-mails - termish at were ocounsel. All turned the thumb drive that did not have my family information but had the information related to the - to this case.  Q. And what kinds of documents to this case.  Q. And what kinds of documents  They would circulate the minutes from the from the REMS meetings, the agenda, the participants.  They would circulate the minutes for comments to make sure that they reflected heard.  A. Yes.  Q. And turning to your e-mails - termish at were open documents with add the information related to the - to this case.  Q. And what kinds of documents to counsel. All turned the thumb drive?  A. Oh, they were things like	4 .	Q. What search terms did you	4	Q. So just to clarify, you		
you know they were listed in your document there, opioids, oxymorphone, 9 Opana, REMS.  Q And where on your computer 10 Q. And you turned those documents over to your counsel?  A I searched my desktop, and I searched in my in my folders. And I 13 searched in my in my folders. And I 13 searched in through my e-mails. The majority of my e-mails were, shall I say, 14 searched the thumb drive that I use. I 15 also searched in through my e-mails. The majority of my e-mails were, shall I say, 16 combination of junk mail that you get 17 a combination of junk mail that you get 18 from, you know, people soliciting your 19 participation in things not related to 19 this case, you know, just regular, 19 everyday coupons and that type of thing. 21 The other e-mails in my 23 files were copied to the folks at the 24 REMS, now Syncos, previously Campbell 24 REMS, again, they are also copied on the 3 Syncos/in/Ventiv documents since they're 10 attendance at that meeting and take 12 minutes. 7 Q. And when did you run the 13 my 16 family medical situation that we've been 16 dealing with for about five years, and 17 prepared presented the documents to 2 counsel this past week. 13 I also made a copy of the 16 relevant because I have a we have a 15 family medical situation that we've been dealing with for about five years, and 17 pecause I don't have a formal job, I and that single thumb drive that I used 19 for, you know, family personal, medical, 20 fo	5		5	* * *		
you know they were listed in your document there, opioids, oxymorphone, 9 Opana, REMS.  Q And where on your computer 10 Q. And you turned those documents over to your counsel?  A I searched my desktop, and I searched in my in my folders. And I 13 searched in my in my folders. And I 13 searched in through my e-mails. The majority of my e-mails were, shall I say, 14 searched the thumb drive that I use. I 15 also searched in through my e-mails. The majority of my e-mails were, shall I say, 16 combination of junk mail that you get 17 a combination of junk mail that you get 18 from, you know, people soliciting your 19 participation in things not related to 19 this case, you know, just regular, 19 everyday coupons and that type of thing. 21 The other e-mails in my 23 files were copied to the folks at the 24 REMS, now Syncos, previously Campbell 24 REMS, again, they are also copied on the 3 Syncos/in/Ventiv documents since they're 10 attendance at that meeting and take 12 minutes. 7 Q. And when did you run the 13 my 16 family medical situation that we've been 16 dealing with for about five years, and 17 prepared presented the documents to 2 counsel this past week. 13 I also made a copy of the 16 relevant because I have a we have a 15 family medical situation that we've been dealing with for about five years, and 17 pecause I don't have a formal job, I and that single thumb drive that I used 19 for, you know, family personal, medical, 20 fo	6	A. Anything related to opioids,	6	A. Yes.		
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1 , , & &	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	REMS, again, they are also copied on the Syneos/inVentiv documents since they're in attendance at that meeting and take minutes.  Q. And when did you run the search in your e-mail?  A. Between the time I received the subpoena and the time that I prepared presented the documents to counsel this past week.  I also made a copy of the relevant because I have a we have a family medical situation that we've been dealing with for about five years, and because I don't have a formal job, I don't work for a company any longer, I had that single thumb drive that I used for, you know, family personal, medical, business, as well as anything that was	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	the minutes from the from the REMS meetings, the agenda, the participants. They would circulate the minutes for comments to make sure that they reflected accurately what people who participated heard.  It contained the I believe there was a copy of the MedBiquitous REMS specs on there, which was another element of the REMs.  Q. I'm sorry, I think I missed the word you said before "REMS."  A. MedBiquitous. It's the Johns Hopkins organization that does the metrics for the REMS.  Q. Any other categories of documents on the thumb drive?  A. Those are that's the majority of them.		
22 - F	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	REMS, again, they are also copied on the Syneos/inVentiv documents since they're in attendance at that meeting and take minutes.  Q. And when did you run the search in your e-mail?  A. Between the time I received the subpoena and the time that I prepared presented the documents to counsel this past week.  I also made a copy of the relevant because I have a we have a family medical situation that we've been dealing with for about five years, and because I don't have a formal job, I don't work for a company any longer, I had that single thumb drive that I used for, you know, family personal, medical, business, as well as anything that was relating to my consulting work on the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the minutes from the from the REMS meetings, the agenda, the participants. They would circulate the minutes for comments to make sure that they reflected accurately what people who participated heard.  It contained the I believe there was a copy of the MedBiquitous REMS specs on there, which was another element of the REMs.  Q. I'm sorry, I think I missed the word you said before "REMS."  A. MedBiquitous. It's the Johns Hopkins organization that does the metrics for the REMS.  Q. Any other categories of documents on the thumb drive?  A. Those are that's the majority of them.  And there may have been, for		
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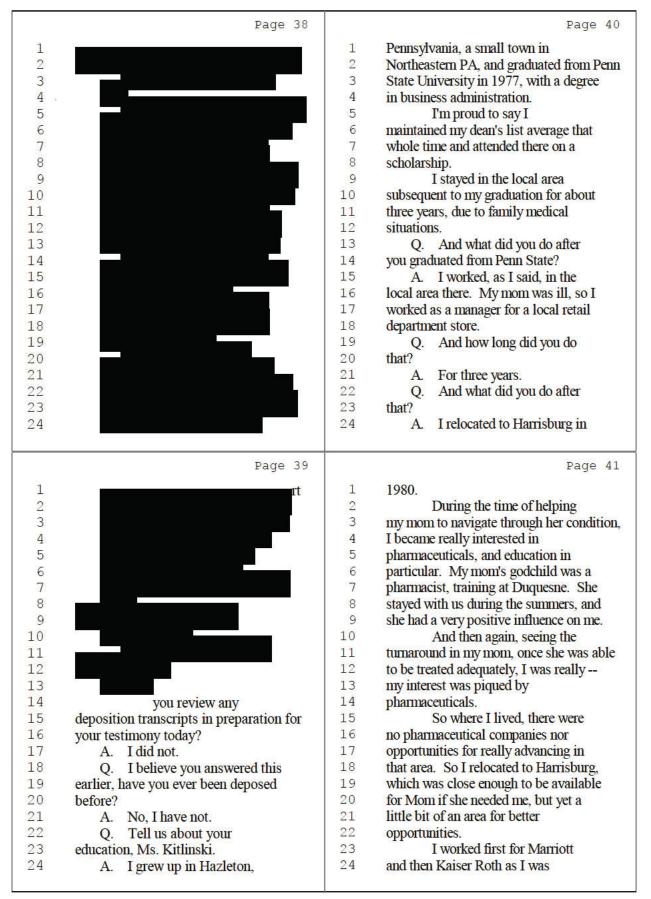
Page 22 Page 24 1 1 let's say the FDA public meeting. I would A. I provided all of the 2 have printed out a copy at that -- you 2 documents to counsel in January. 3 know, at that time, of the agenda and any 3 I also provided the one attachments, and afterwards I might have 4 notebook that I had during that time 4 had a copy of it retained on the thumb 5 period after, you know, 2016 until the 5 drive or the directions to the, you know, 6 present, until the end of this past year. 6 7 meeting and things like that. 7 And I provided that notebook to counsel. 8 Q. And you talked about running 8 Q. And -- thank you. 9 the search on the thumb drive. 9 You mentioned your e-mails, Can you give us a better 10 that you searched your e-mails as well 10 sense of when you ran the search? You 11 and you applied the search terms in 11 said it was between October and this 12 plaintiffs' subpoena to your e-mails. 12 13 week, and January, correct? 13 What's your e-mail address? A. LindaKitlinski@gmail.com. 14 MR. DAVIS: Objection to 14 15 I'm sorry, Linda A, there's another A in 15 form. MS. AMINOLROAYA: You can 16 there. 16 17 17 Q. And how long have you answer. maintained this e-mail address? 18 MR. DAVIS: You can go 18 19 19 A. That's been my e-mail ahead. 20 20 address since I retired from Endo, so the BY MS. AMINOLROAYA: 21 Q. Unless your counsel 21 middle of May 2014. 22 instructs you not to answer a question, 22 Q. And to be clear, you did not 23 and that shouldn't occur very 23 have this Gmail e-mail address before May 2.4 frequently --24 of 2014; is that right? Page 23 Page 25 A. Sure. A. I had a Gmail address, I 1 1 2 Q. -- you can answer the 2 never used it. It was -- it was Linda 3 3 Kitlinski, there was no A in it. And so questions. 4 A. Sure. 4 it was inactive, and that's why, when I 5 tried to establish one. I had to include 5 Again, I focused on -- well, 6 I initially started with the paper files, 6 the initial A, because it said that it 7 and I did that in the end of October and 7 was already assigned to someone. But I 8 finished it up this month. Originally, 8 couldn't remember my password, so --9 the subpoena said that the deposition 9 Q. Understood. That happens. would be held in November, but because of 10 And were there any other 10 11 my dad's medical situation, I appreciated 11 e-mails you maintained besides the Linda 12 the flexibility in being able to do it 12 Kitlinski Gmail account? this month instead. So I had begun some 13 13 A. Not since leaving Endo. 14 things and finished them up this month. 14 Endo had my, you know, Endo e-mail And the computer, you know, 15 address. But since leaving the company, 15 looking through the documents on my -- in 16 16 17 my files on the thumb drive, that was in 17 Q. And while you were at Endo, 18 were there any other personal e-mail 18 January. 19 addresses you maintained? Q. And did you provide any 19 documents to your counsel before January? A. No. I had just one e-mail 20 20 21 A. No. I did not. address, and that was my Endo address. 21 22 Q. Documents that were on the 22 O. And you used that for all 23 thumb drive or on your computer, were 23 communications? 24 those provided to counsel before January? 24 A. Yes, I did.

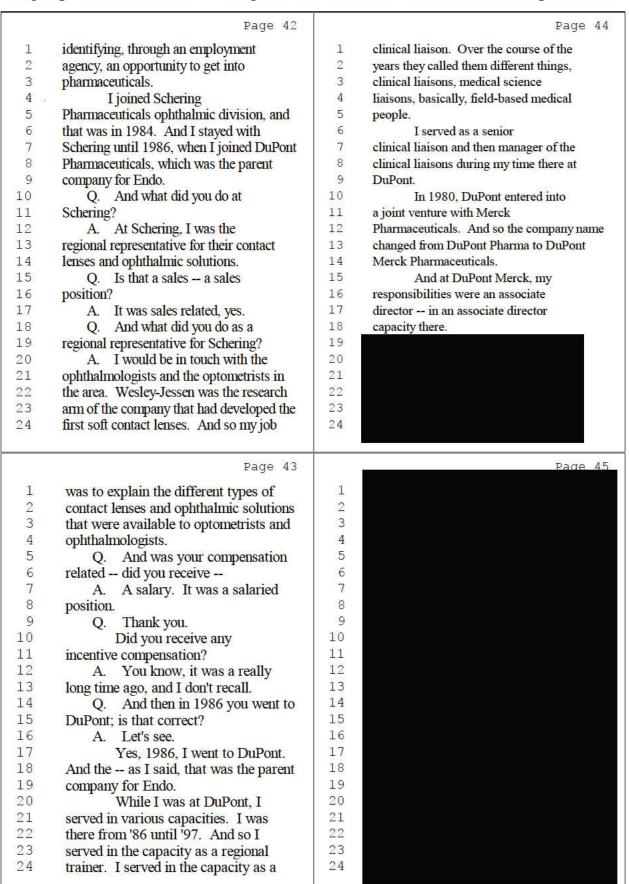


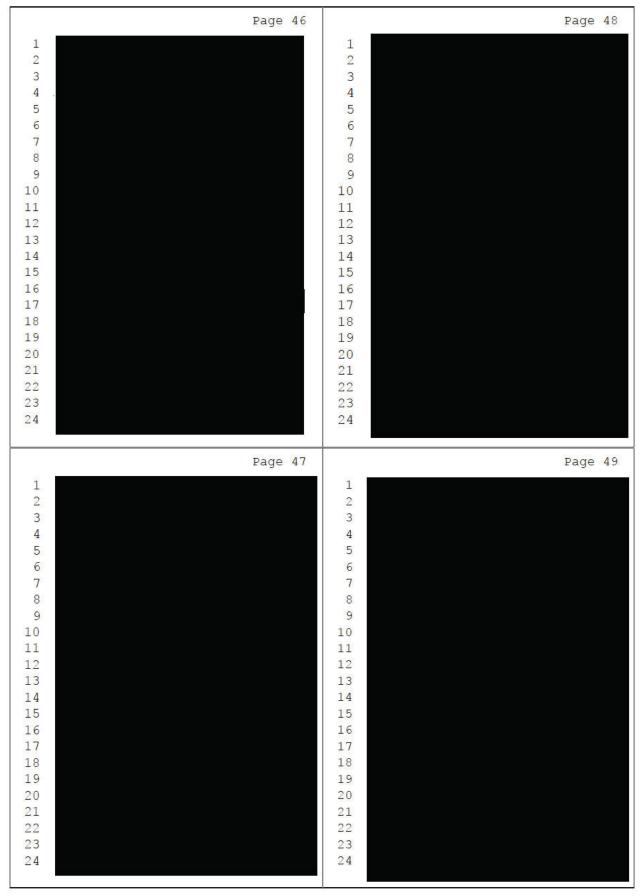


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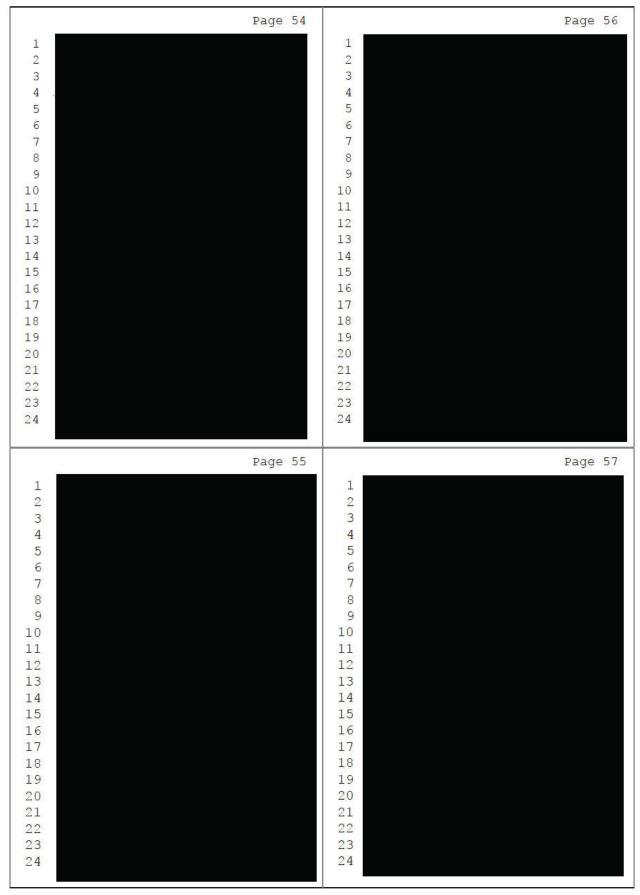




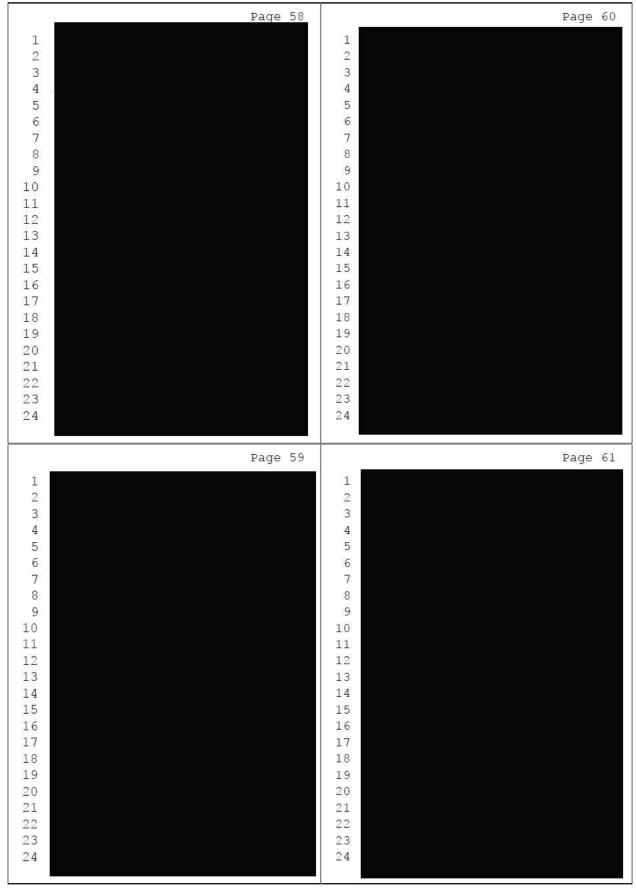
13 (Pages 46 to 49)



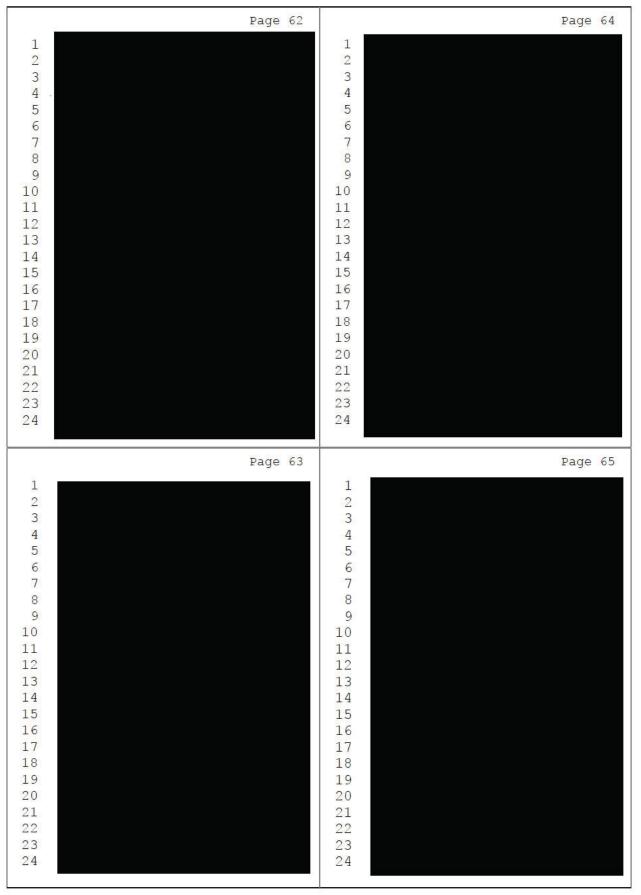
14 (Pages 50 to 53)



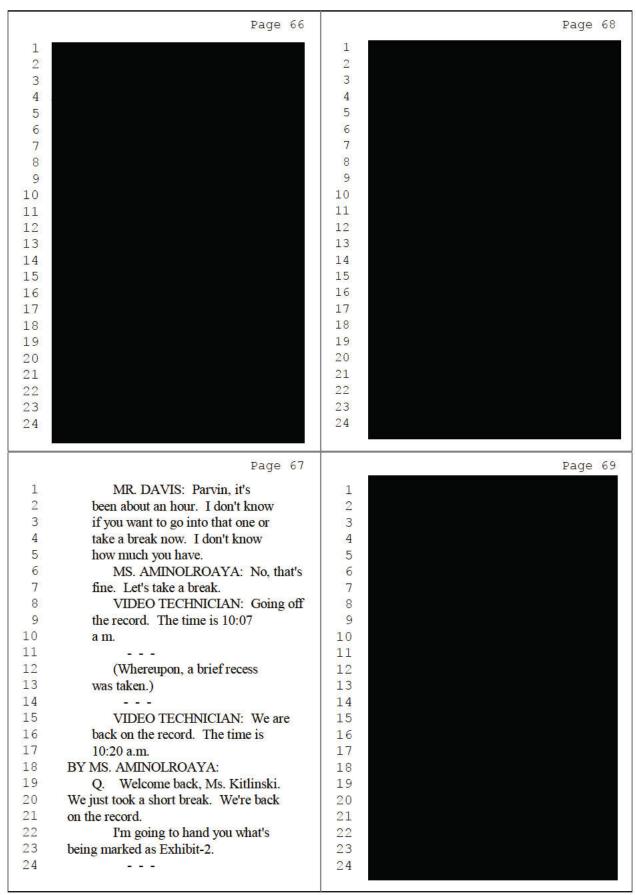
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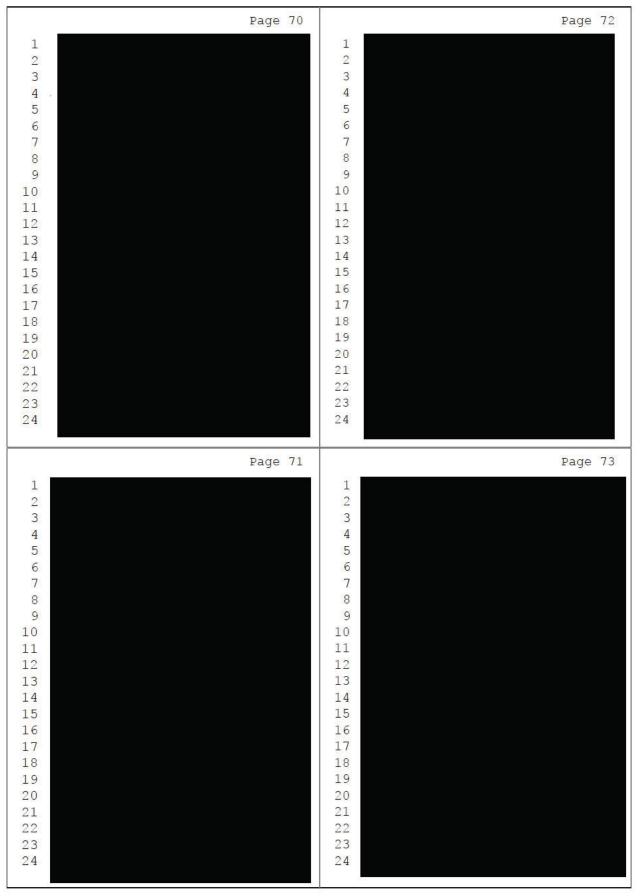
16 (Pages 58 to 61)



17 (Pages 62 to 65)



18 (Pages 66 to 69)



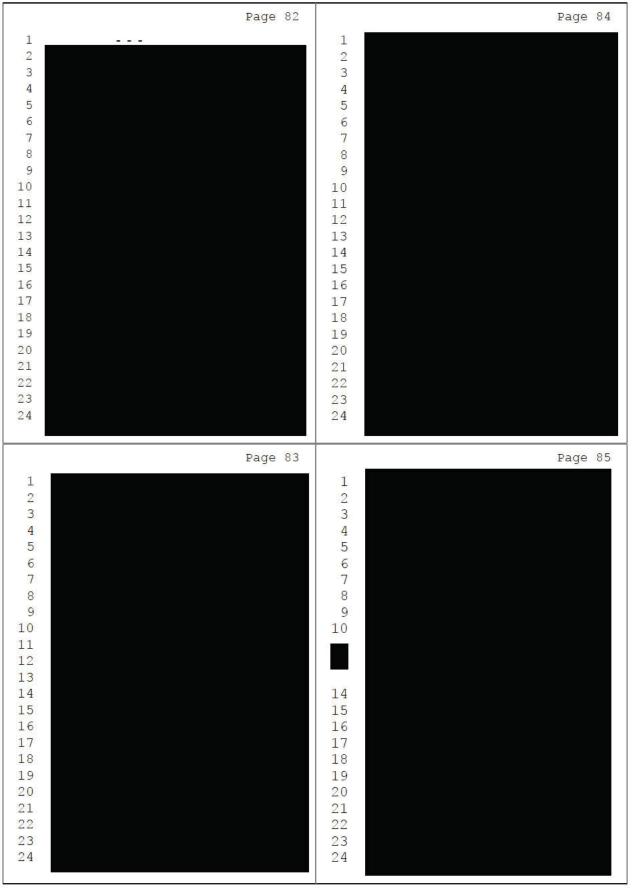
19 (Pages 70 to 73)



20 (Pages 74 to 77)



21 (Pages 78 to 81)



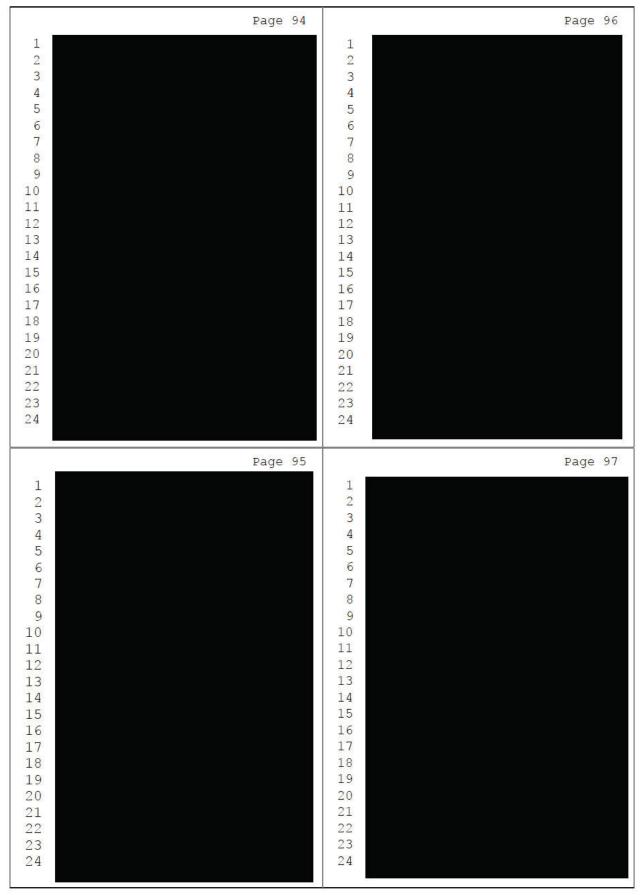
22 (Pages 82 to 85)



23 (Pages 86 to 89)

	Page 90	9	Page 92
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	
	Page 91		Page 93
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	

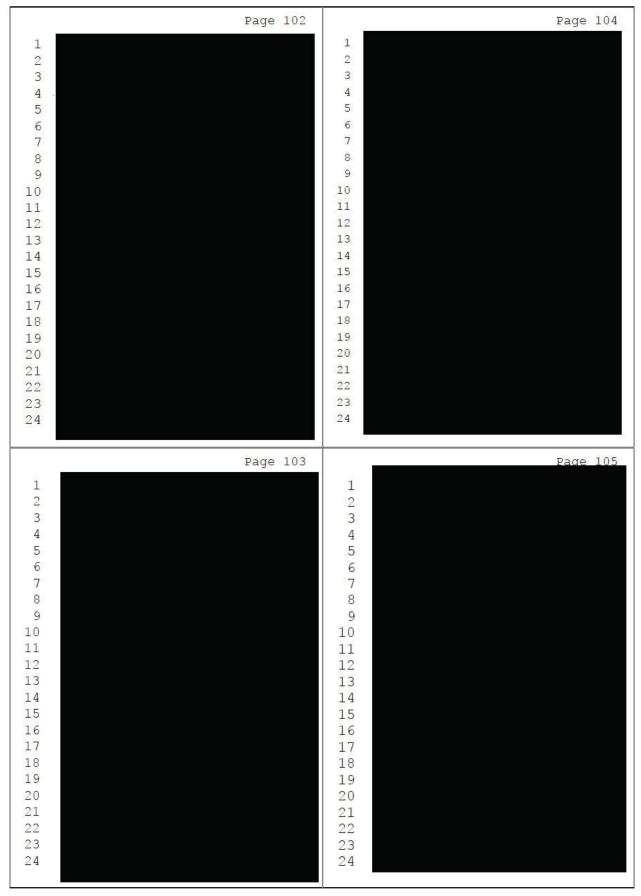
24 (Pages 90 to 93)



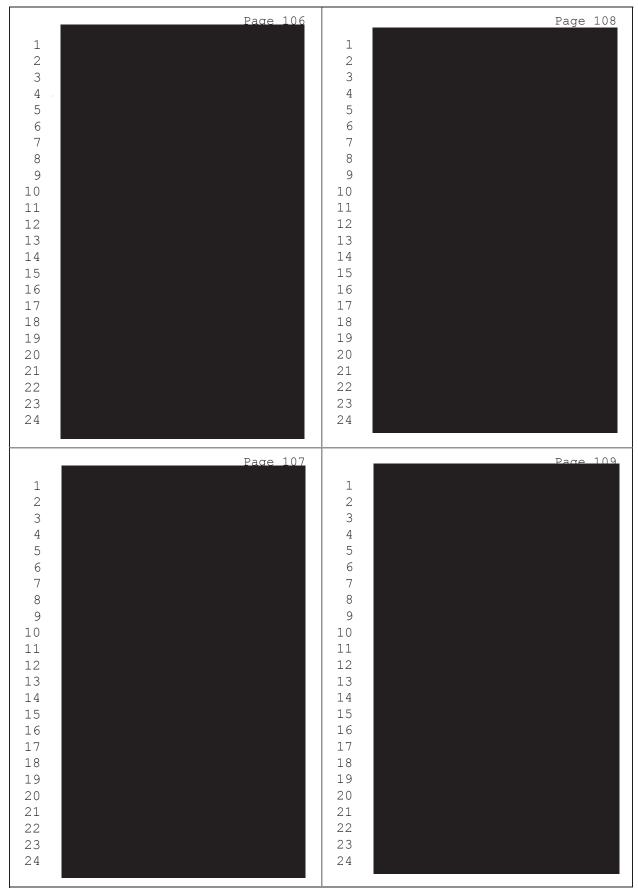
25 (Pages 94 to 97)

	Page 98		Page 100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	
	Page 99		Page 101
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	

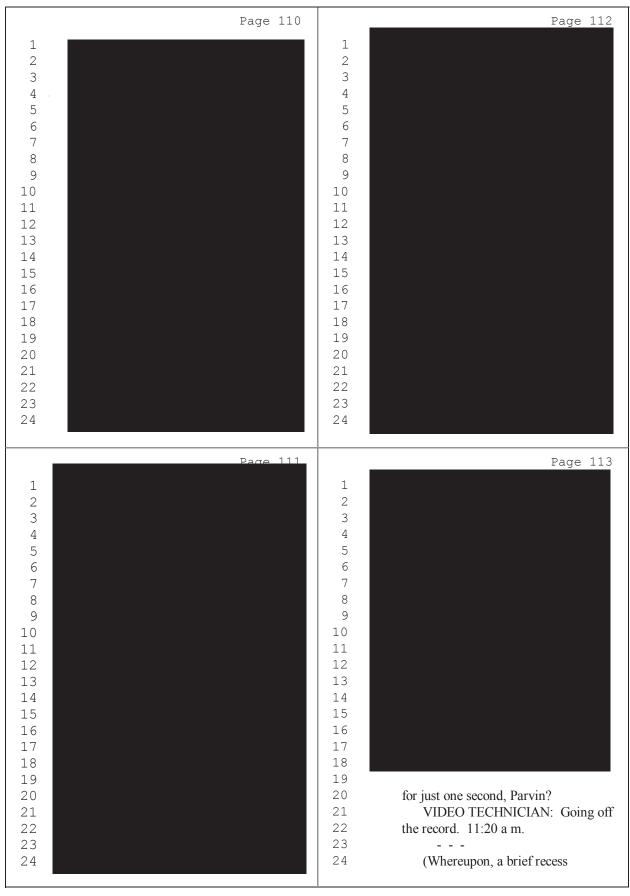
26 (Pages 98 to 101)



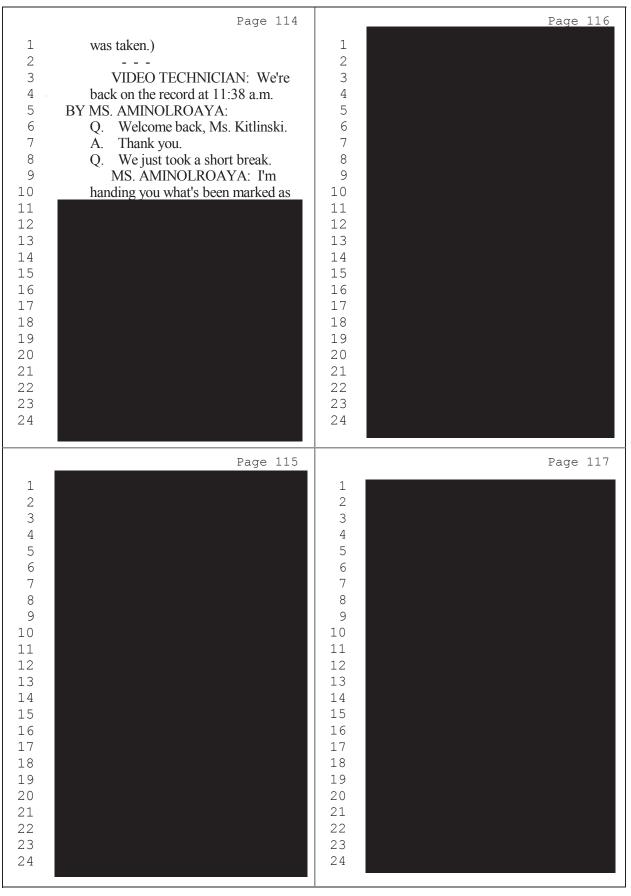
27 (Pages 102 to 105)



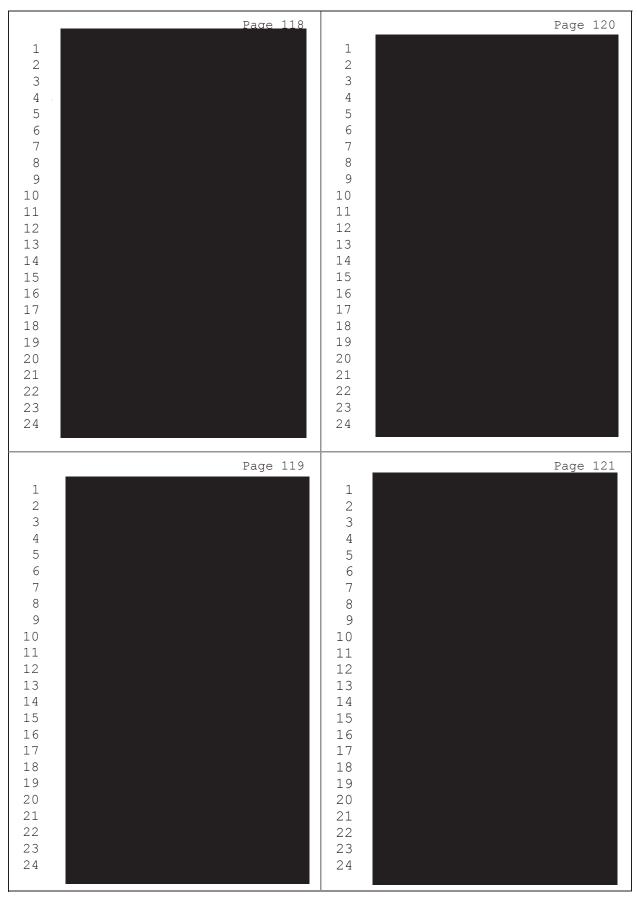
28 (Pages 106 to 109)



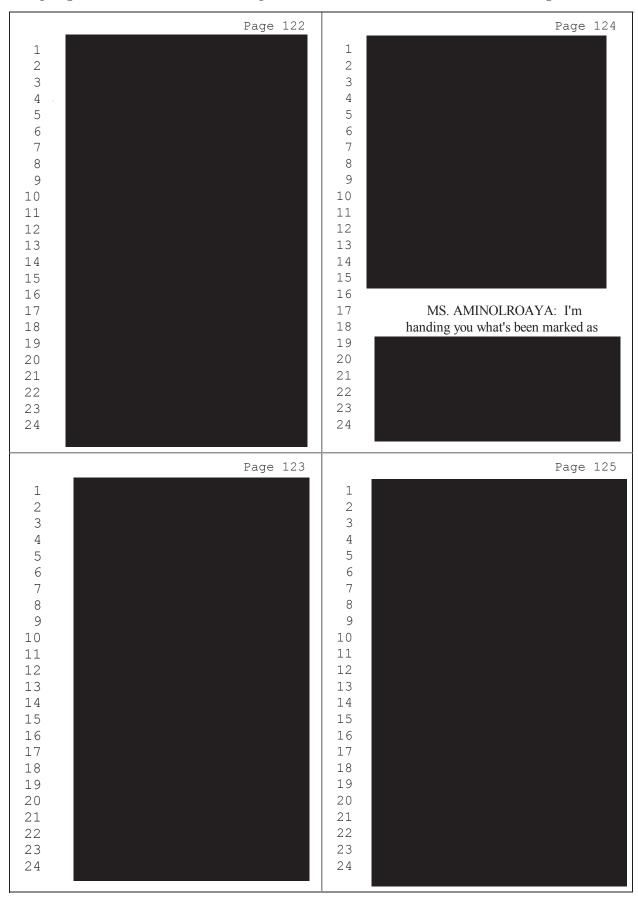
29 (Pages 110 to 113)



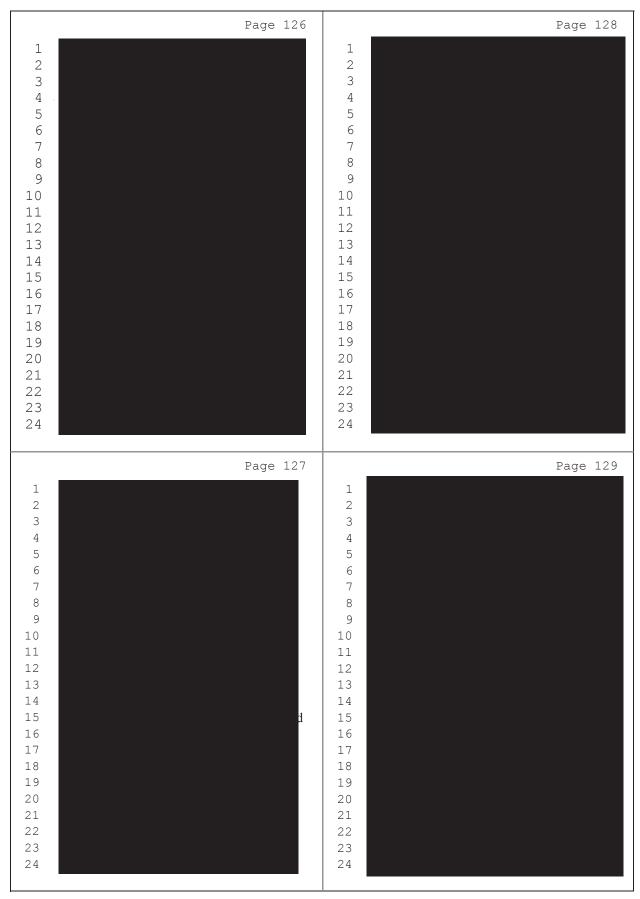
30 (Pages 114 to 117)



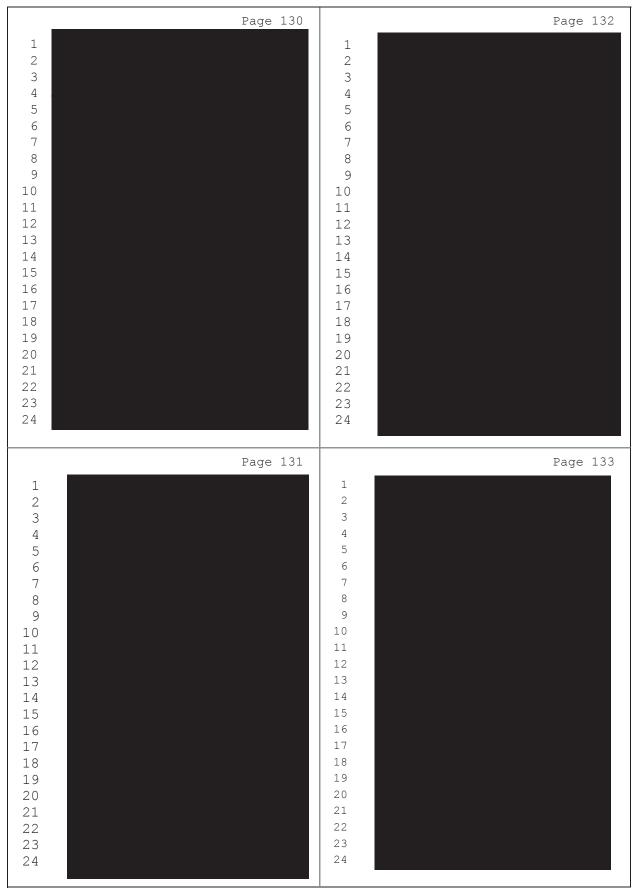
31 (Pages 118 to 121)



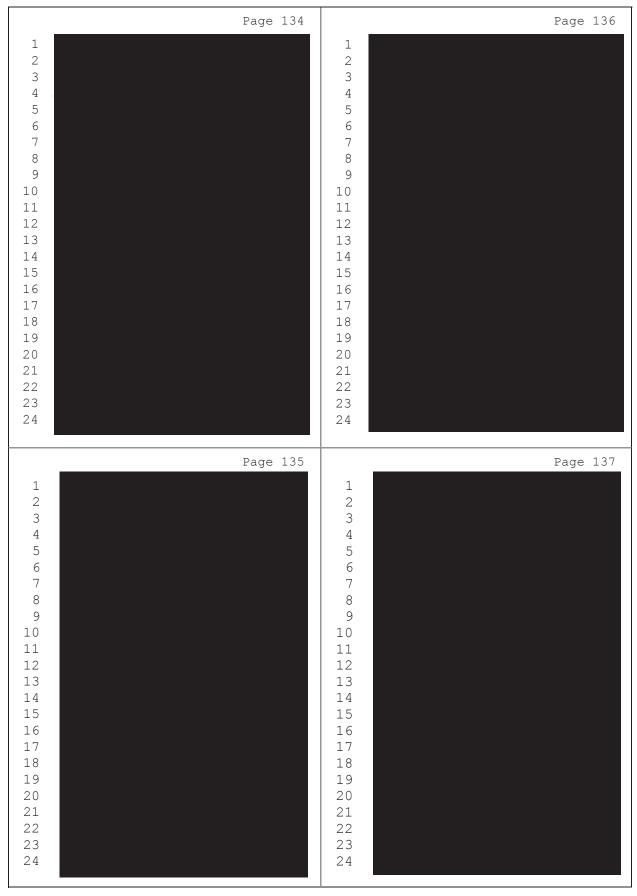
32 (Pages 122 to 125)



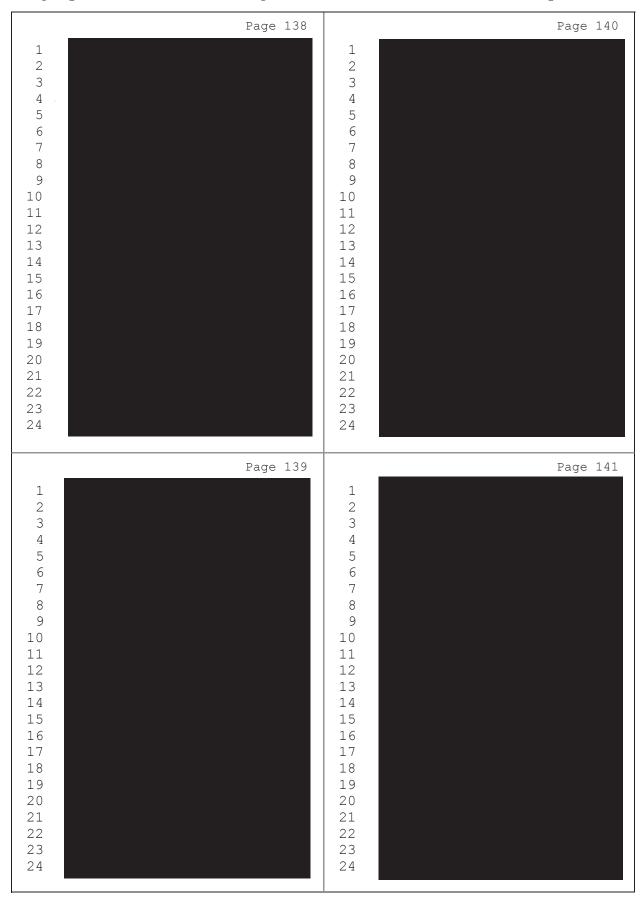
33 (Pages 126 to 129)



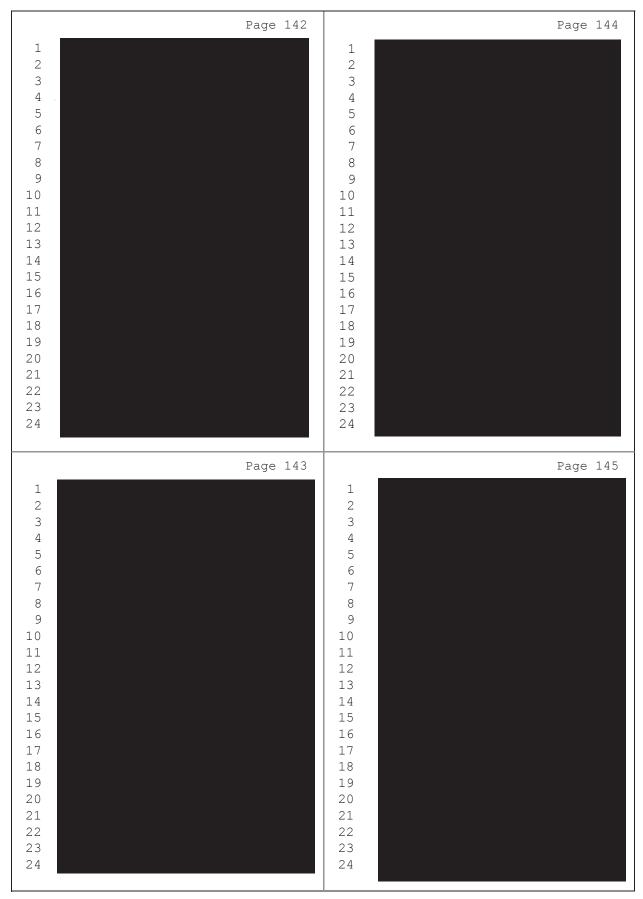
34 (Pages 130 to 133)



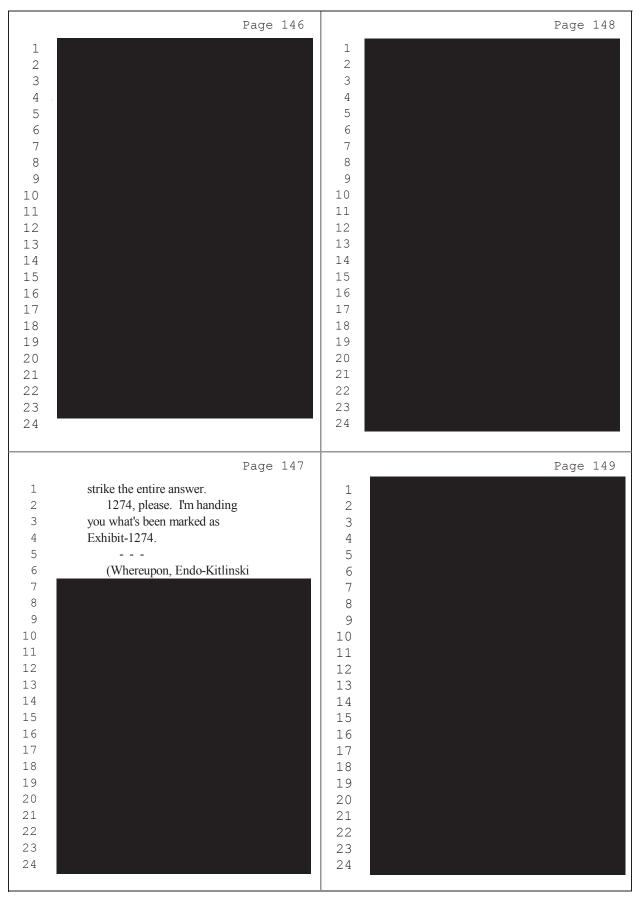
35 (Pages 134 to 137)



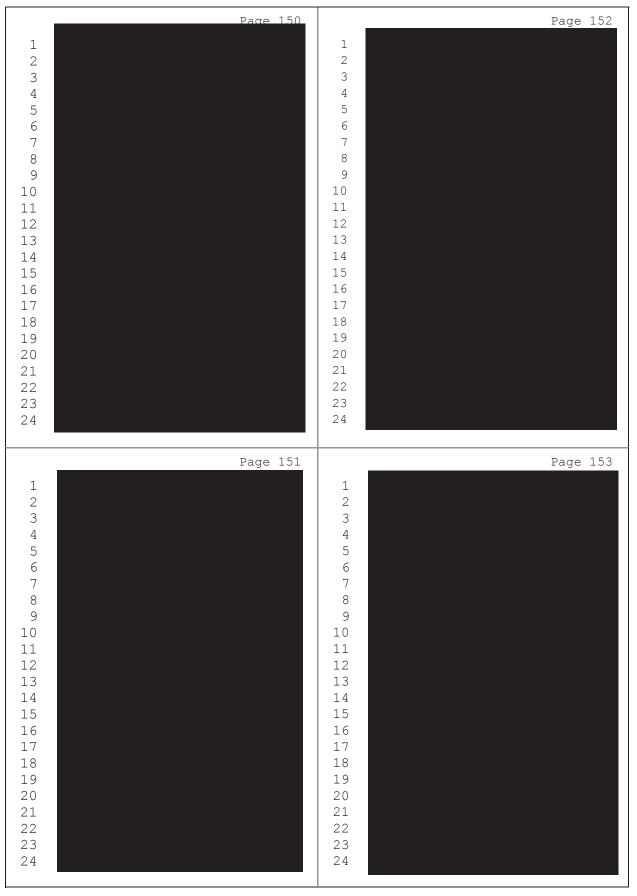
36 (Pages 138 to 141)



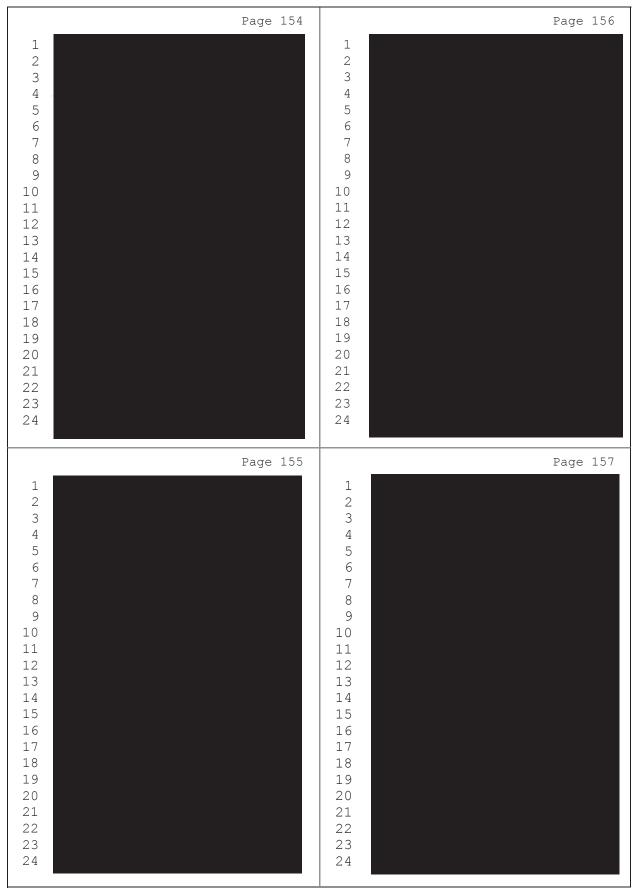
37 (Pages 142 to 145)



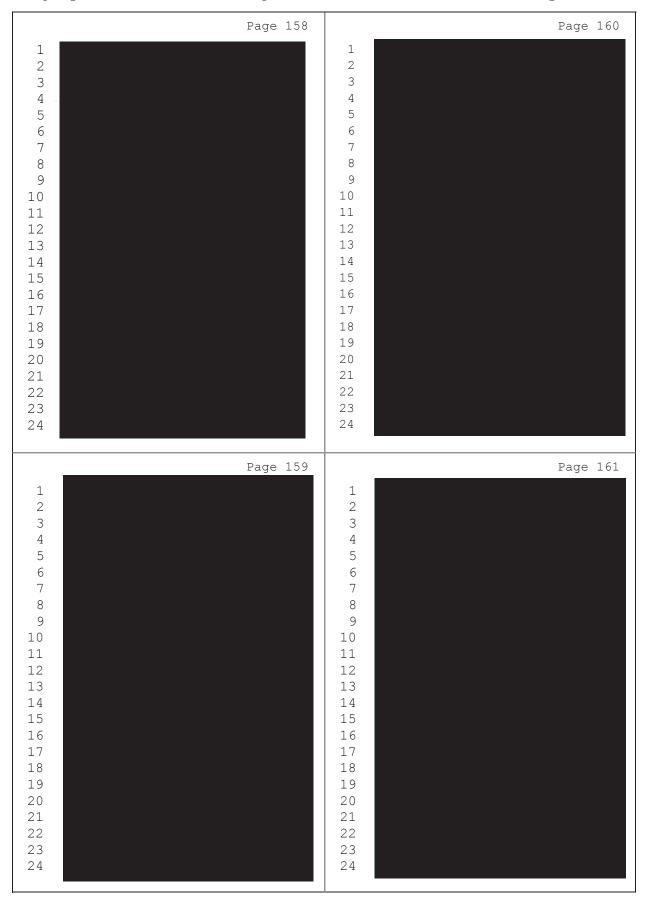
38 (Pages 146 to 149)



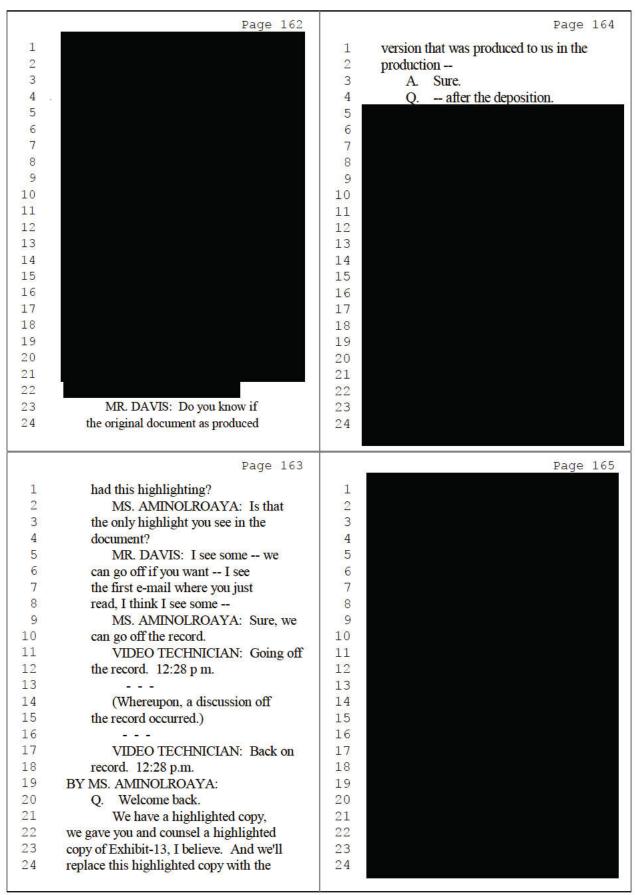
39 (Pages 150 to 153)



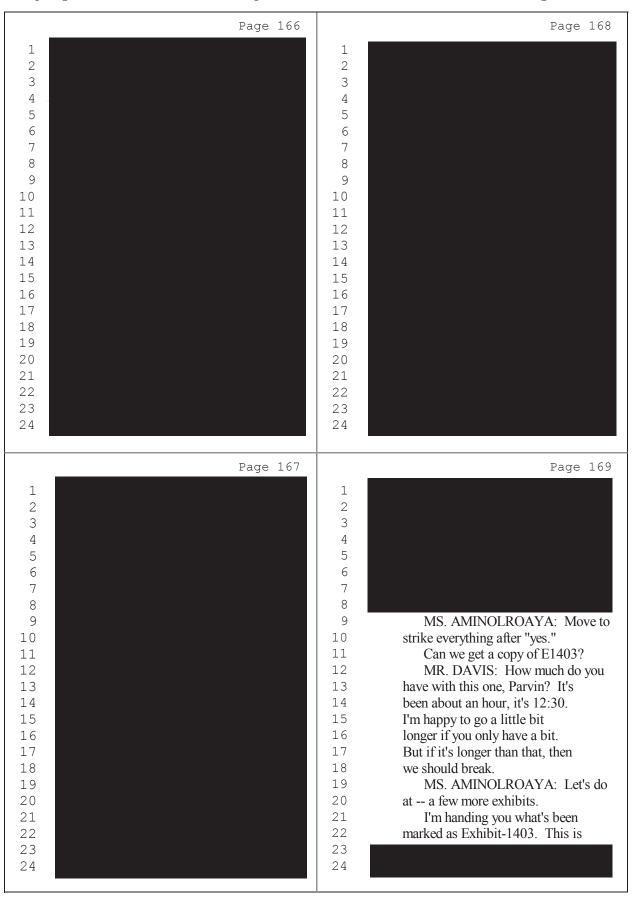
40 (Pages 154 to 157)



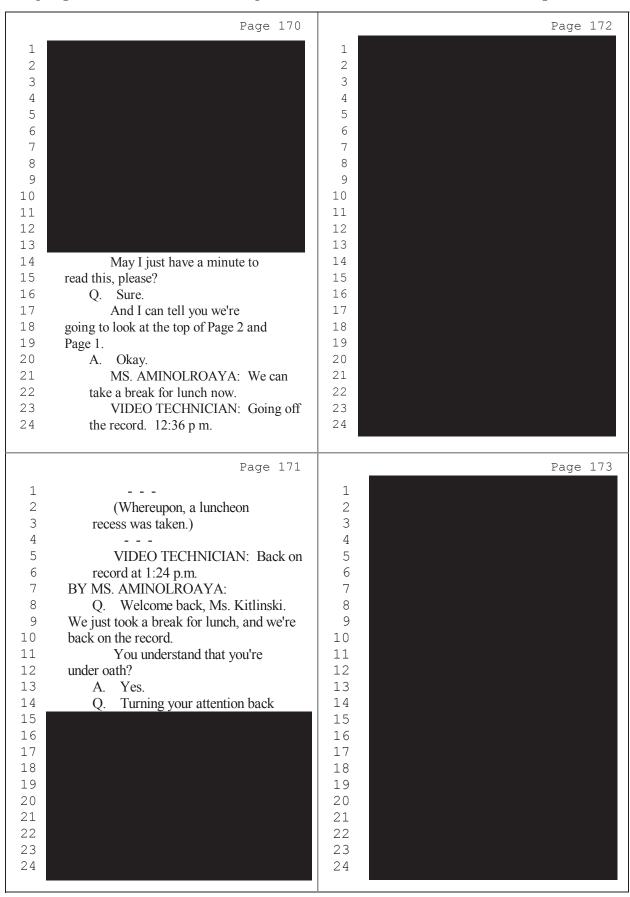
41 (Pages 158 to 161)



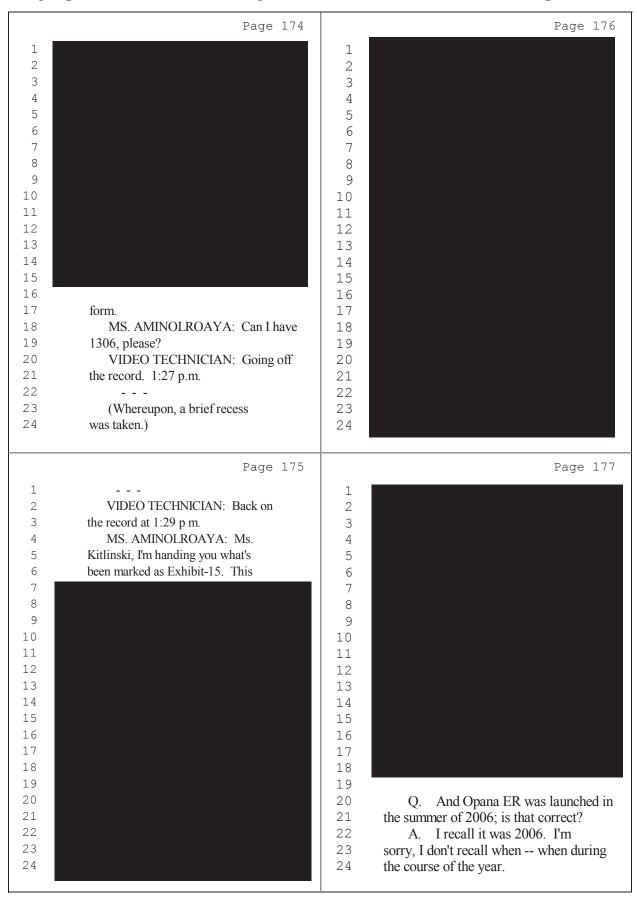
42 (Pages 162 to 165)



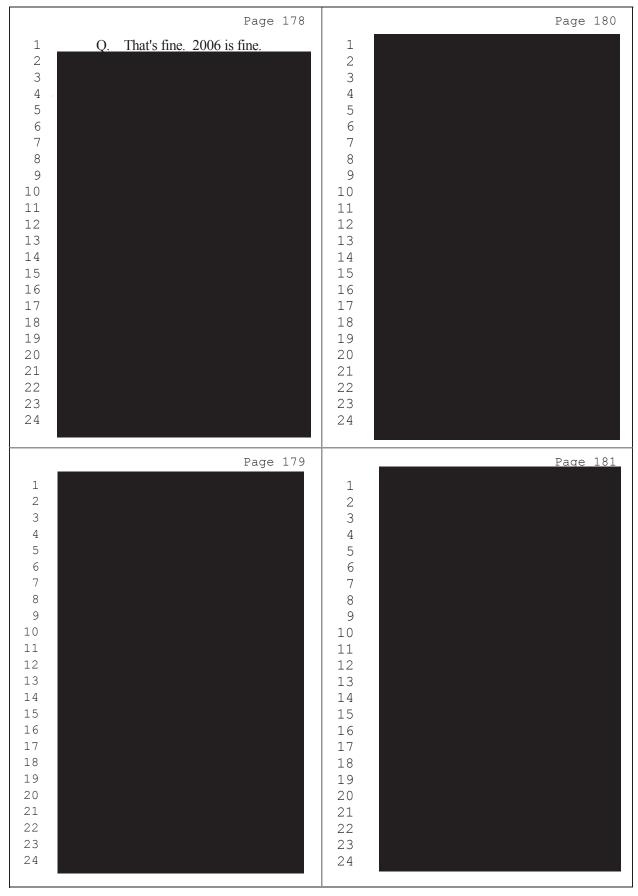
43 (Pages 166 to 169)



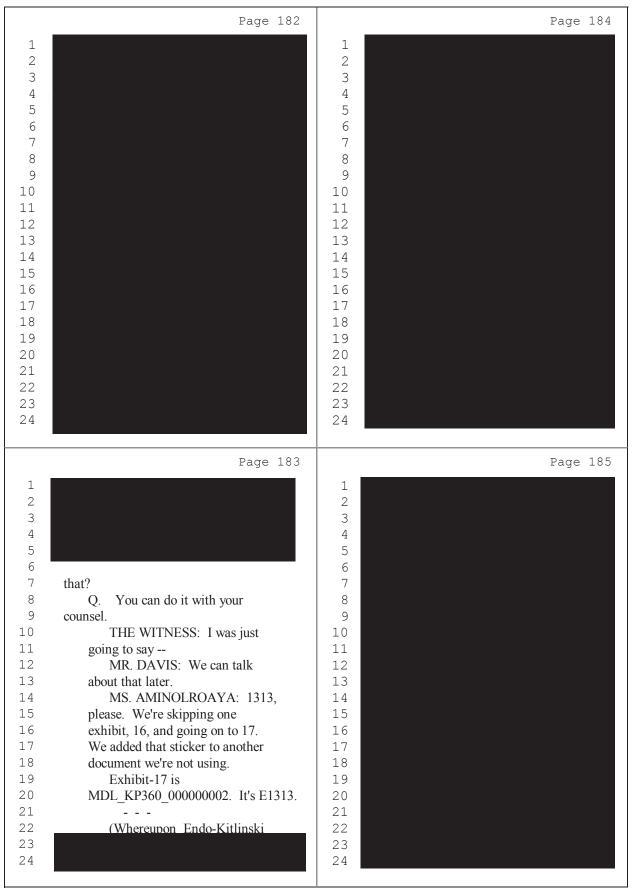
44 (Pages 170 to 173)



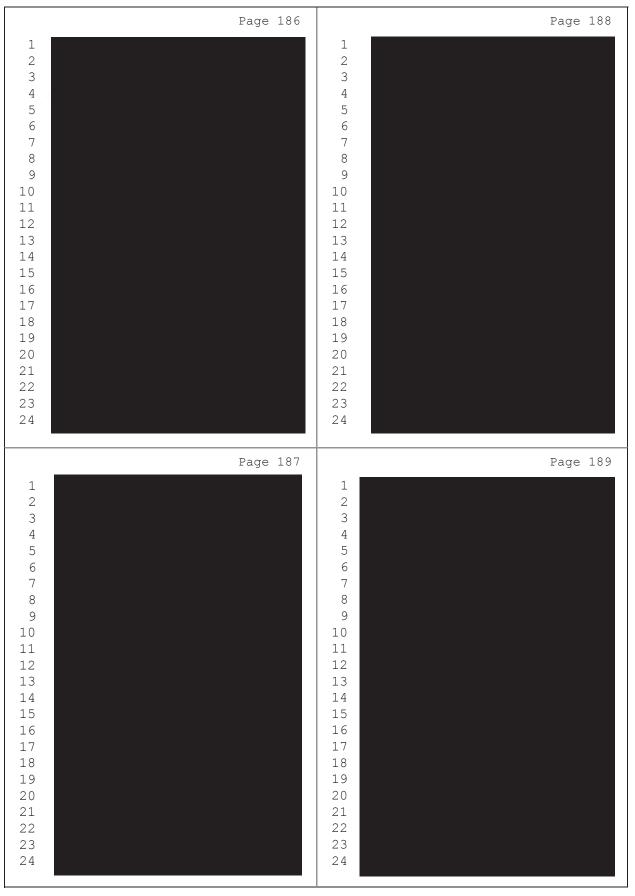
45 (Pages 174 to 177)



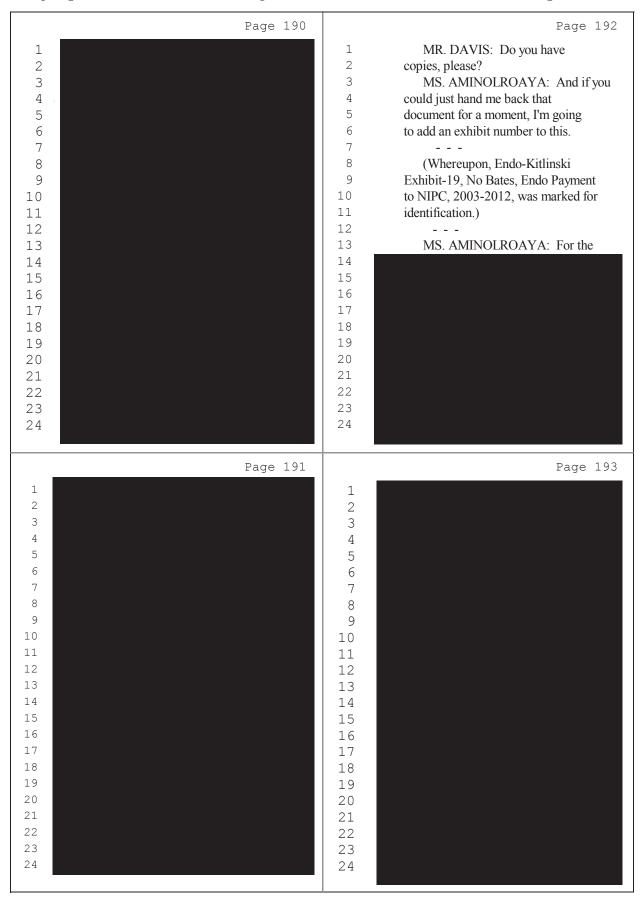
46 (Pages 178 to 181)



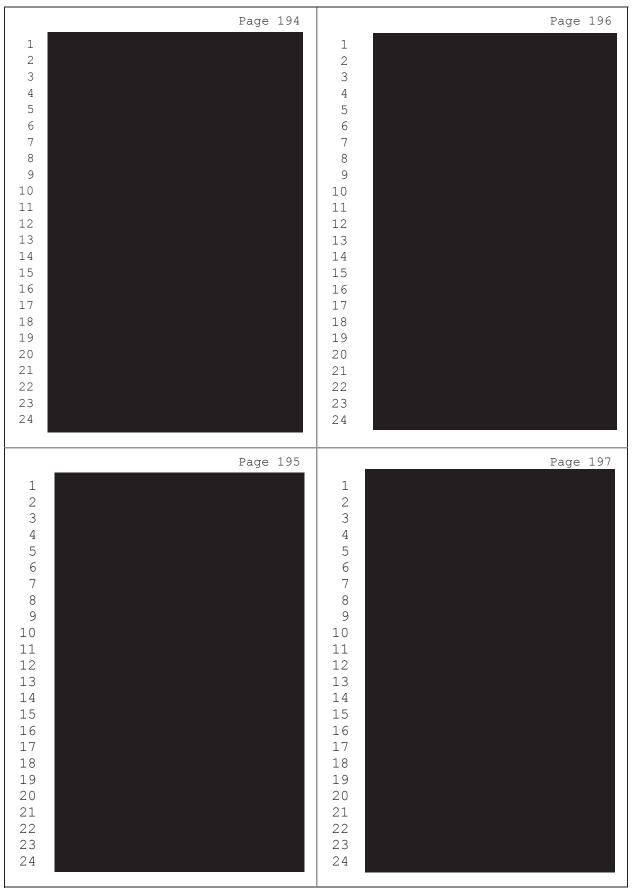
47 (Pages 182 to 185)



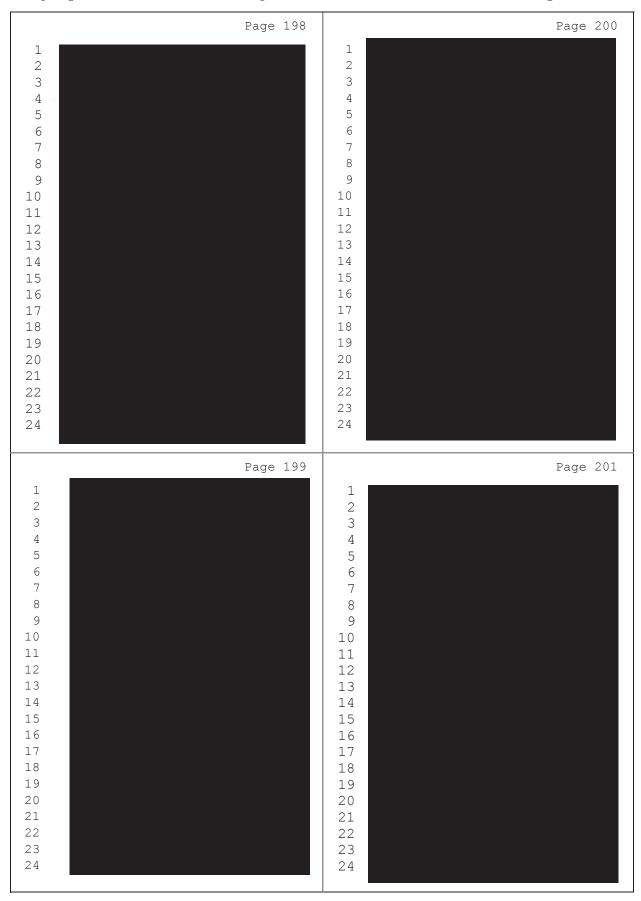
48 (Pages 186 to 189)



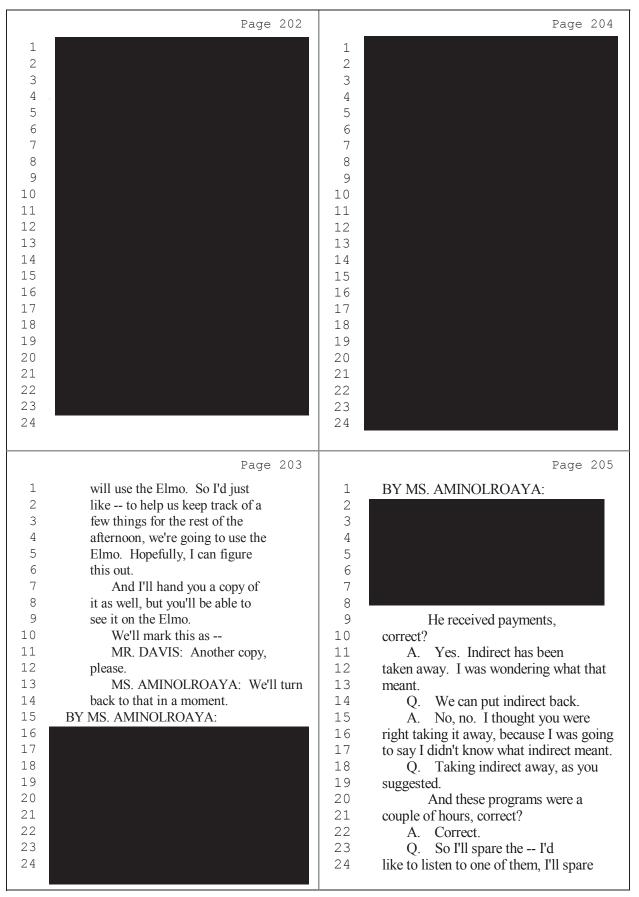
49 (Pages 190 to 193)



50 (Pages 194 to 197)

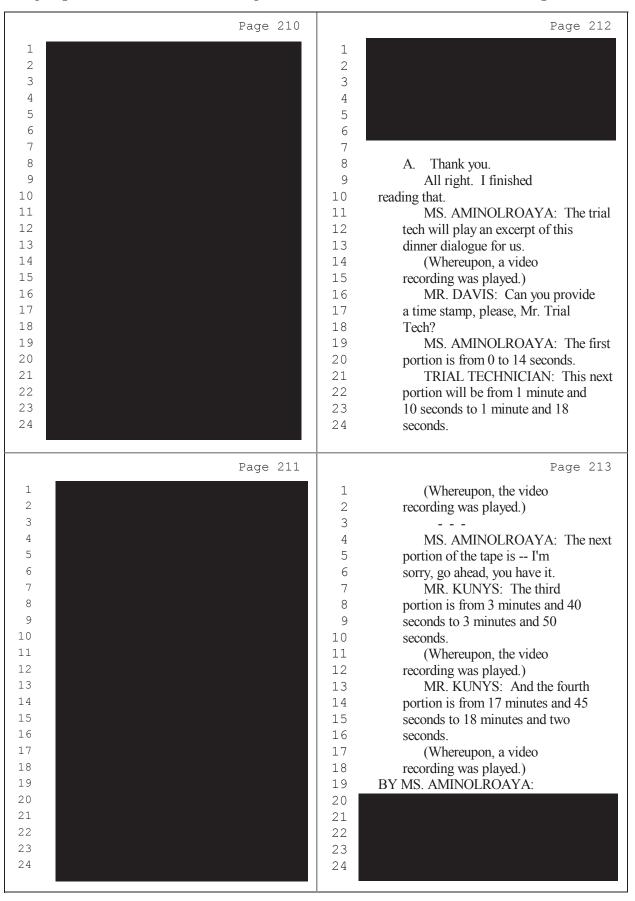


51 (Pages 198 to 201)

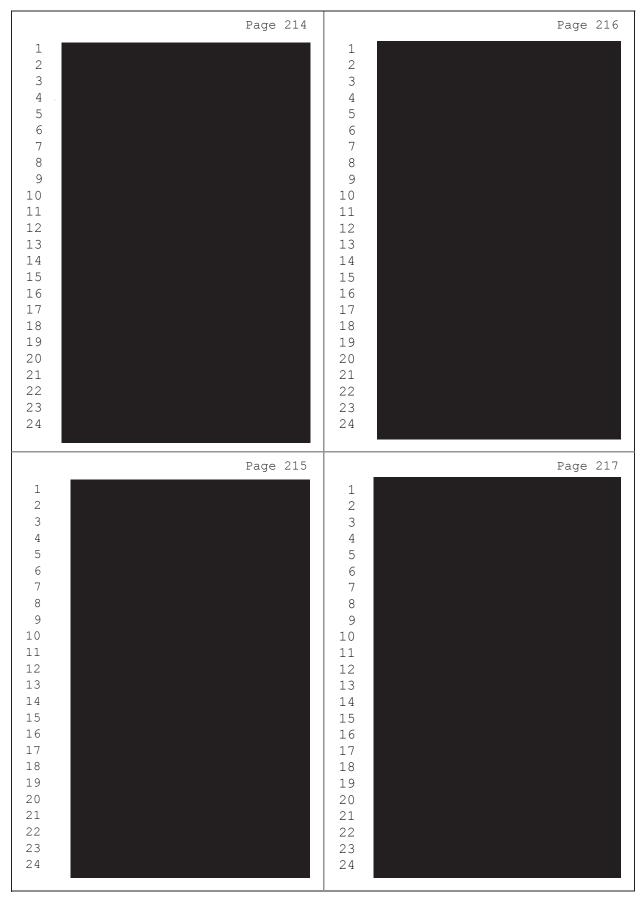


52 (Pages 202 to 205)

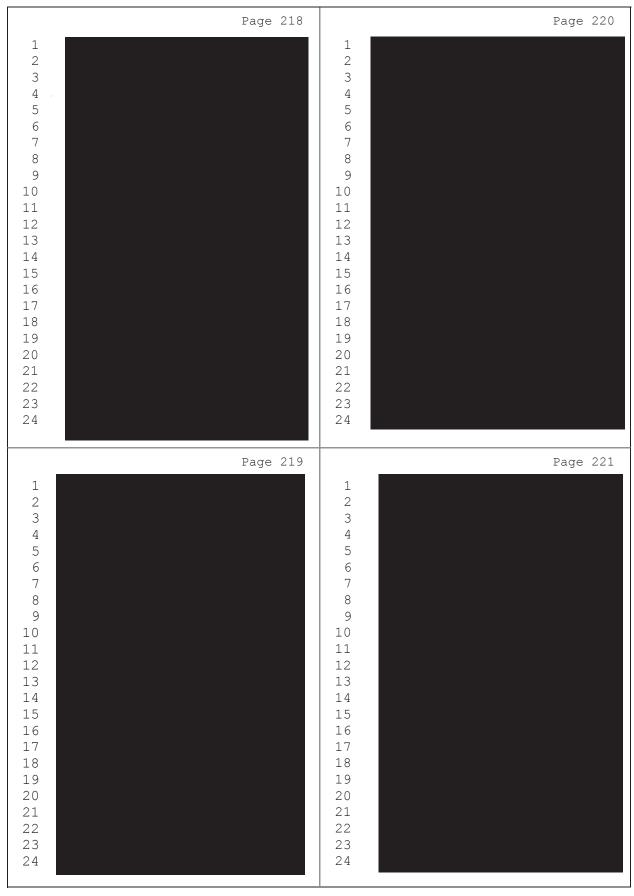
	Page 206		Page 208
1	the jury from listening to the full	1	And that's not going to be on the
2	presentation, but we'll play a portion of	2	record. So let's go off for a
3	Dr. Argoff and Dr. Ford's presentation at	3	second, please.
4 .	one of the NIPC dinners, Advances in	4	MR. BUCHANAN: Who's your
5	Opioid Analgesia, Maximizing Benefit and	5	client? You work for Endo, not
6	Minimizing Risks.	6	for Ms. Kitlinski.
7	MR. DAVIS: You're going to	7	MR. DAVIS: I do work for
8	play a recording of the	8	Ms. Kitlinski as well.
9	MS. AMINOLROAYA: CME, yes.	9	But let's we're going to
10	MR. DAVIS: And you're just	10	go off the record for this
11	going to play a portion of it, not	11	conversation.
12	the entire thing?	12	VIDEO TECHNICIAN: Going off
13	MS. AMINOLROAYA: Yes.	13	the record. The time is 2:02 p.m.
14	MR. DAVIS: Are you going to	14	
15	ask Ms. Kitlinski questions about	15	(Whereupon, a brief recess
16	the portions you're about to play?	16	was taken.)
17	MS. AMINOLROAYA: Yes.	17	
18	MR. DAVIS: I'm going to	18	VIDEO TECHNICIAN: We're
19	object to Ms. Kitlinski answering	19	back on record. The time is 2:06
20	any questions about the portion of	20	p m.
21	a dinner dialogue, without	21	MR. DAVIS: So prior to any
22	listening to the entire thing.	22	questioning about the excerpt or
23	That's the same as showing her	23	snippet of whatever recording you
24	about one page of a ten-page	24	intend to play, I just want to
	Page 207		Page 209
1	document. She's got to have the	1	lodge an objection for the record.
2	whole thing for the full context.	2	We're going to permit Ms.
3	MR. BUCHANAN: I disagree,	3	Kitlinski to answer questions, but
4	counsel. Ms. Kitlinski attended	4	we think it's highly inappropriate
5	hours and hours of meetings.	5	to be asking her questions about
6	She's not being asked for	6	just portions of some recording
7	everything that happened in hours	7	that you're representing was a
8	and hours of meetings.	8	recording from NIPC, some dinner
9	MR. DAVIS: I don't know	9	dialogue. It's no different than
10	what she's going to be asked about	10	asking her about a single page of
11	and I don't know what the context	11	a ten-page document without
12	of what you're about to play is.	12	letting her review the entire
13	MR. BUCHANAN: You're	13	document.
14	objection is noted.	14	So we think all of these
15	MR. DAVIS: I don't know	15	questions about this recording are
16	what I'm not going to let Ms.	16	inappropriate, are objectionable.
17	Kitlinski can we go off the	17	But we're going to permit Ms.
18	record for a second?	18	Kitlinski to answer.
19	MR. BUCHANAN: No, it should	19	BY MS. AMINOLROAYA:
20	be on the record.	20	
21	MS. AMINOLROAYA: It should	21	
22	be on the record.	22	
	MR. DAVIS: I'd like to talk	23	
23			
23 24	to my client about this, if I may.	24	



54 (Pages 210 to 213)

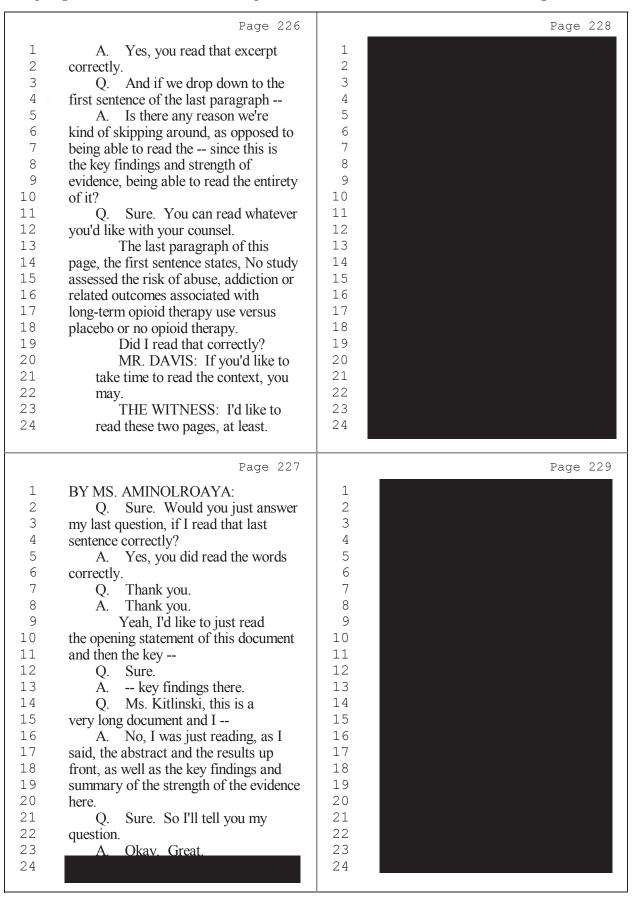


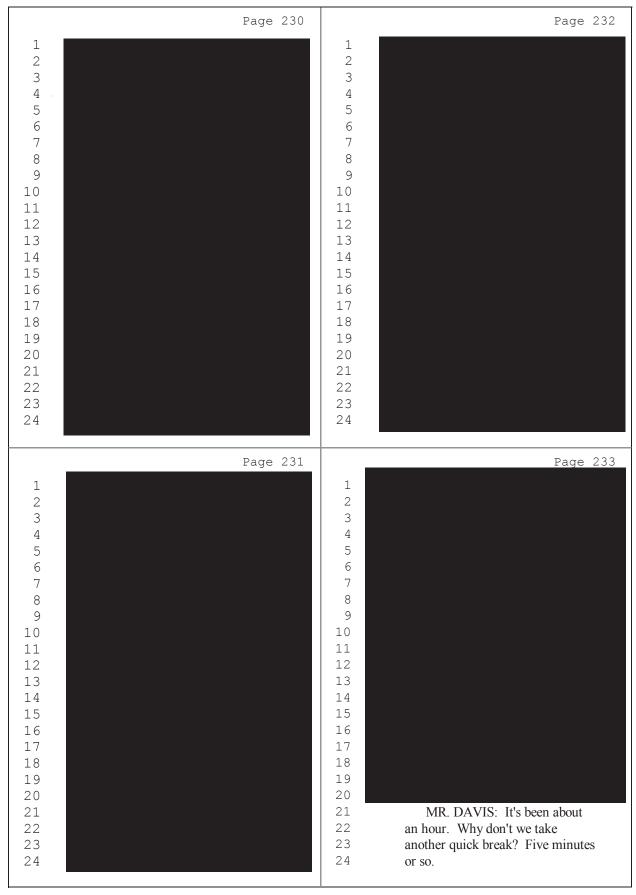
55 (Pages 214 to 217)



56 (Pages 218 to 221)

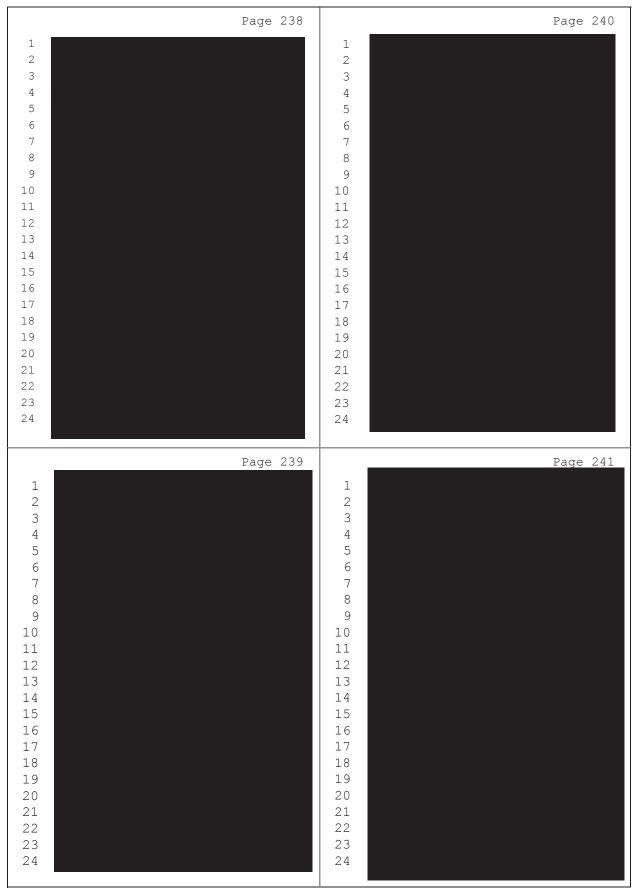
	Page 222		Page 224
1		1	Objectives. Chronic pain is common and
2		2	use of long-term opioid therapy for
3		3	chronic pain has increased dramatically.
4 .		4	This report reviews the current evidence
5		5	on effectiveness and harms of opioid
6		6	therapy for chronic pain, focusing on
7		7	long-term (longer than one year)
8		8	outcomes.
9		9	And to orient us, I should
10	MS. AMINOLROAYA: Can I get	10	have mentioned this before, the bottom of
11	1304, please?	11	Page 2 contains the date of September
12	I'm handing you what's been	12	2014. And this was prepared for the
13	marked as Exhibit-24. It's E770.	13	Agency for Healthcare Research and
14	This is the evidence	14	Quality, U.S. Department of Health and
15	report/technology assessment,	15	Human Services, prepared by Pacific
16	Number 218, The Effectiveness and	16	Northwest Evidence-Based Practice Center,
17	Risks of Long-Term Opioid	17	Oregon Health and Science University.
18	Treatment and Chronic Pain.	18	Did I read that correctly?
19	Prepared by The Agency for	19	A. Yes.
20	Healthcare Research and Quality.	20	Q. Now turning to Page 9.
21		21	And the objective there, did
22	(Whereupon, Endo-Kitlinski	22	I read that correctly before?
23	Exhibit-24, No Bates, The	23	I can read it one more time.
24	Effectiveness and Risks of	24	It says, Chronic pain is common and use
	- 000		
	Page 223		Page 225
1	_	1	
1 2	Long-Term Opioid Treatment of	1 2	of long-term opioid therapy for chronic
	_	1	of long-term opioid therapy for chronic pain has increased dramatically. This
2	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and	2	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on
2	Long-Term Opioid Treatment of Chronic Pain; Agency for	2 3	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy
2 3 4	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for	2 3 4	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on
2 3 4 5	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.)	2 3 4 5	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term
2 3 4 5 6	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the	2 3 4 5 6	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.
2 3 4 5 6 7	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to	2 3 4 5 6 7	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?
2 3 4 5 6 7 8	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA:	2 3 4 5 6 7 8 9	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes.  Q. Turning to Page 33 of the document.
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2 3 4 5 6 7 8 9 10 11 12	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare	2 3 4 5 6 7 8 9 10 11 12	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes. Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence.
2 3 4 5 6 7 8 9 10 11 12 13	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare Research and Quality, known as AHRQ?	2 3 4 5 6 7 8 9 10 11 12 13	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes. Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence. Second paragraph states, For
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare Research and Quality, known as AHRQ? A. I'm familiar with that organization. And I'm familiar, generally, with this document. But I	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes.  Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence. Second paragraph states, For effectiveness and comparative effectiveness, we identified no studies of long-term opioid therapy in patients
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare Research and Quality, known as AHRQ? A. I'm familiar with that organization. And I'm familiar, generally, with this document. But I haven't read it in detail.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes.  Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence. Second paragraph states, For effectiveness and comparative effectiveness, we identified no studies of long-term opioid therapy in patients with chronic pain versus no opioid
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare Research and Quality, known as AHRQ? A. I'm familiar with that organization. And I'm familiar, generally, with this document. But I haven't read it in detail. Q. Okay. Let's turn to Page 33	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes. Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence. Second paragraph states, For effectiveness and comparative effectiveness, we identified no studies of long-term opioid therapy in patients with chronic pain versus no opioid therapy or nonopioid alternative
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare Research and Quality, known as AHRQ? A. I'm familiar with that organization. And I'm familiar, generally, with this document. But I haven't read it in detail. Q. Okay. Let's turn to Page 33 of the document actually, before we do that, let's turn to Page 9 at the top, 770.9.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes.  Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence. Second paragraph states, For effectiveness and comparative effectiveness, we identified no studies of long-term opioid therapy in patients with chronic pain versus no opioid therapy or nonopioid alternative therapies that evaluated outcomes at one year or longer. No studies examined how effectiveness varies based on various
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare Research and Quality, known as AHRQ? A. I'm familiar with that organization. And I'm familiar, generally, with this document. But I haven't read it in detail. Q. Okay. Let's turn to Page 33 of the document actually, before we do that, let's turn to Page 9 at the top, 770.9. It says, The Effectiveness	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes.  Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence. Second paragraph states, For effectiveness and comparative effectiveness, we identified no studies of long-term opioid therapy in patients with chronic pain versus no opioid therapy or nonopioid alternative therapies that evaluated outcomes at one year or longer. No studies examined how effectiveness varies based on various factors, including type of pain and pain
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Long-Term Opioid Treatment of Chronic Pain; Agency for Healthcare Research and Quality, was marked for identification.) MR. DAVIS: Just for the record, this doesn't appear to have a Bates number on it. MS. AMINOLROAYA: Correct. BY MS. AMINOLROAYA: Q. Ms. Kitlinski, are you familiar with The Agency for Healthcare Research and Quality, known as AHRQ? A. I'm familiar with that organization. And I'm familiar, generally, with this document. But I haven't read it in detail. Q. Okay. Let's turn to Page 33 of the document actually, before we do that, let's turn to Page 9 at the top, 770.9. It says, The Effectiveness	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of long-term opioid therapy for chronic pain has increased dramatically. This report reviews the current evidence on effectiveness and harms of opioid therapy for chronic pain, focusing on long-term (longer than one year) outcomes.  Did I read that correctly?  A. Yes.  Q. Turning to Page 33 of the document.  It says, Discussion, key findings and strength of evidence. Second paragraph states, For effectiveness and comparative effectiveness, we identified no studies of long-term opioid therapy in patients with chronic pain versus no opioid therapy or nonopioid alternative therapies that evaluated outcomes at one year or longer. No studies examined how effectiveness varies based on various factors, including type of pain and pain



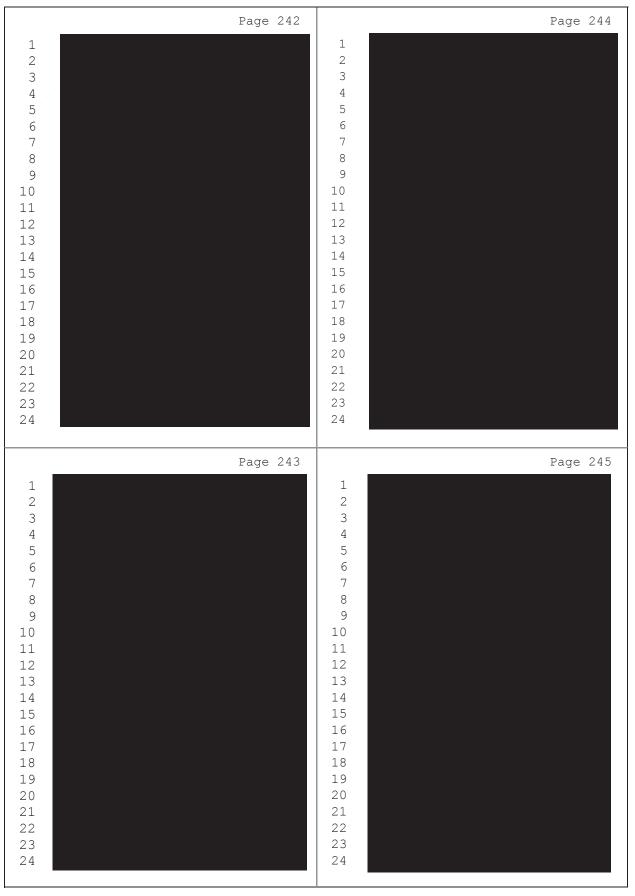


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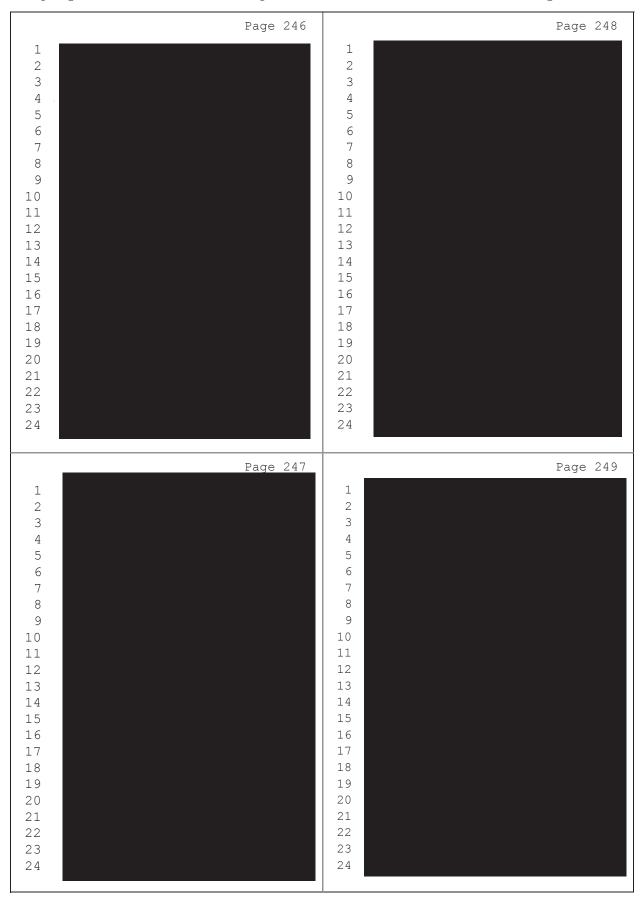
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Page 234
                                                                                            Page 236
 1
               THE WITNESS: That would be
                                                        1
                                                                   Q. And if you turn to Page 4 of
 2
                                                        2
                                                               the document with me, you'll see a page
            great.
 3
                MS. AMINOLROAYA: That's
                                                        3
                                                               entitled, Key Terms for Opioid
 4
                                                        4
                                                               Analgesics.
            fine.
                                                        5
 5
                VIDEO TECHNICIAN: Going off
                                                                       And if you look in the
 6
            the record. The time is 2:32 p.m.
                                                        6
                                                               right-hand column there, you see the term
 7
                                                        7
                                                               pseudoaddiction. It says,
 8
                (Whereupon, a brief recess
                                                        8
                                                               Pseudoaddiction refers to behaviors that
 9
                                                        9
            was taken.)
                                                               might seem aberrant, but actually
                                                      10
10
                                                               indicate inadequate treatment of pain.
                 - - -
                                                               The behaviors resolve when the pain
11
                VIDEO TECHNICIAN: Back on
                                                      11
                                                               medication is increased and appropriate
12
            record at 2:48 p.m.
                                                      12
13
        BY MS. AMINOLROAYA:
                                                      13
                                                               analgesia is obtained.
14
            Q. Ms. Kitlinski, welcome back.
                                                      14
                                                                      Did I read that correctly?
15
        We just took a short break.
                                                      15
                                                                   A. Yes.
16
            A. Thank you.
                                                      16
                                                                   Q. So the NIPC management
            Q. And you had just testified
                                                      17
17
                                                               newsletters were -- included key terms
        that you recalled the newsletter that
18
                                                      18
                                                               for opioid such as pseudoaddiction?
        NIPC put out, correct?
                                                      19
                                                                       MR. DAVIS: Objection to
19
20
            A. Yes, I said that I do recall
                                                      20
                                                                   form.
21
        there was a newsletter. I did not
                                                      21
                                                                      THE WITNESS: The key terms
22
        recall -- you mentioned the title of it,
                                                      22
                                                                   that they included -- as you can
23
        and I don't know that.
                                                      23
                                                                   see up front, the first one was
24
               MS. AMINOLROAYA: I'm
                                                      2.4
                                                                   addiction. So that was put in
                                      Page 235
                                                                                            Page 237
 1
           handing you what's been marked
                                                                  appropriate context.
           Exhibit-25. It's
 2
                                                        2
                                                                     And then physical
 3
           ENDO-OPIOID MDL-01605952. It's
                                                        3
                                                                  dependence, tolerance and
                                                                  pseudoaddiction.
           E690.
 4
                                                        4
                                                        5
                                                                     MS. AMINOLROAYA: 304,
 5
                                                        6
 6
              (Whereupon, Endo-Kitlinski
                                                                  please.
 7
                                                        7
           Exhibit-25,
                                                              BY MS. AMINOLROAYA:
 8
           ENDO-OPIOID MDL-01605952-958, was
                                                       8
           marked for identification.)
                                                        9
 9
10
                _ _ _
                                                      10
11
       BY MS. AMINOLROAYA:
                                                      11
12
           O. This is --
                                                      12
           A. Pain Management Today.
                                                      13
13
14
           Q. -- Pain Management Today.
                                                      14
              It sounds like you recognize
                                                      15
15
       it?
16
                                                      16
17
           A. Yes. Now I do.
                                                      17
18
           Q. Great. And is the faculty
                                                      18
19
       advisor here Dr. Argoff?
                                                      19
           A. Correct.
20
                                                      20
21
           Q. And this is -- you can see
                                                      21
22
       the copyright date is 2001, correct?
                                                      22
       Just below Dr. Argoff's photo.
23
                                                      23
           A. Yes.
24
                                                      24
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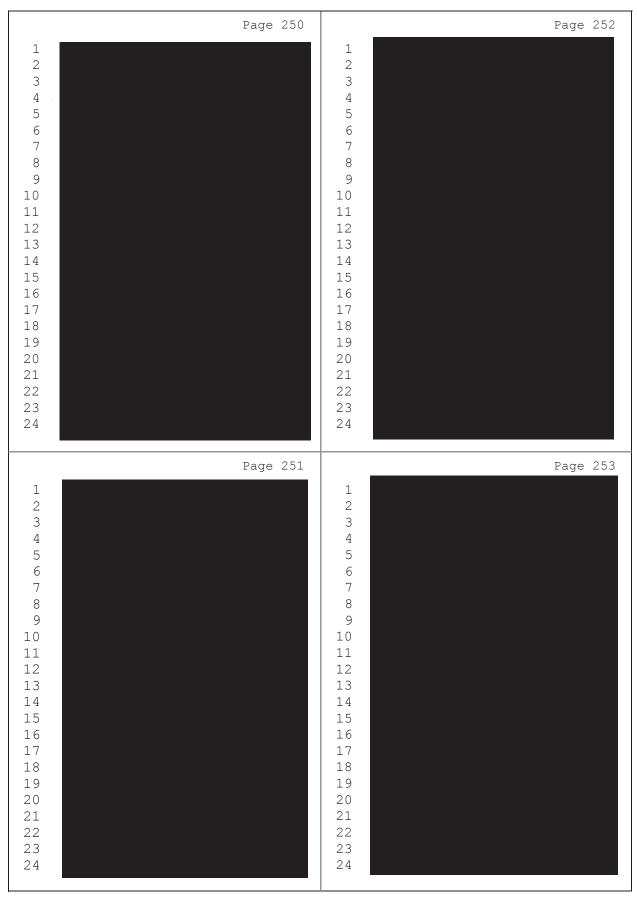
61 (Pages 238 to 241)



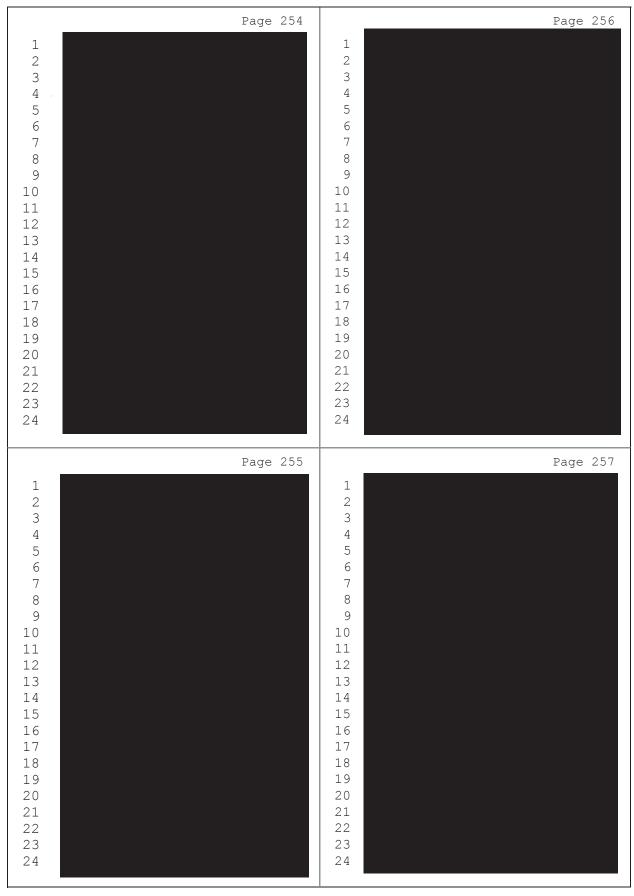
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63 (Pages 246 to 249)

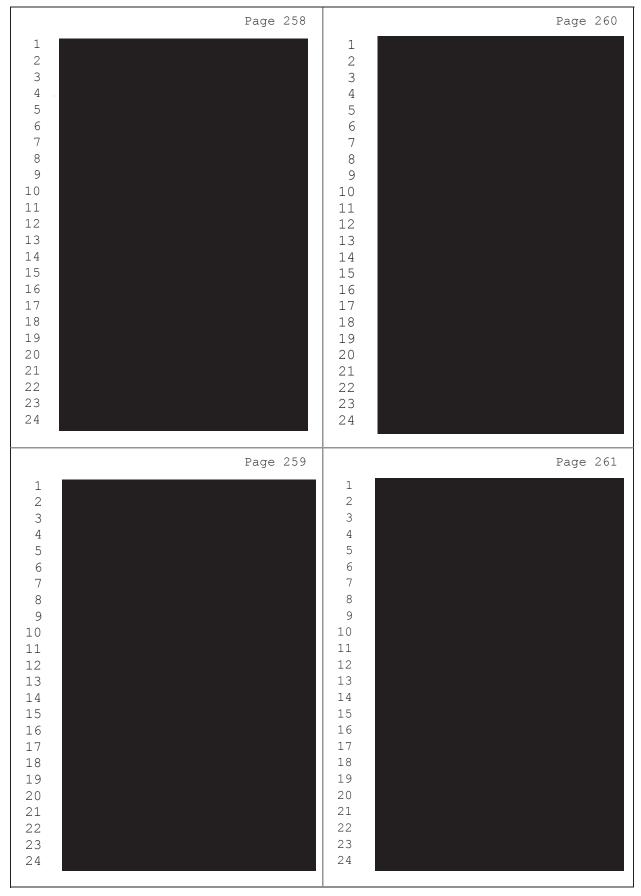


64 (Pages 250 to 253)

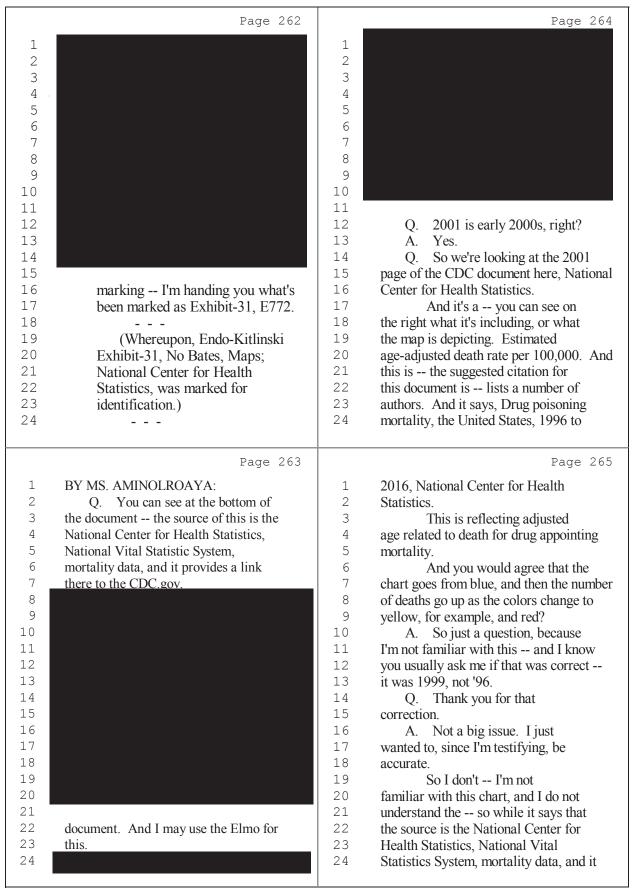


65 (Pages 254 to 257)

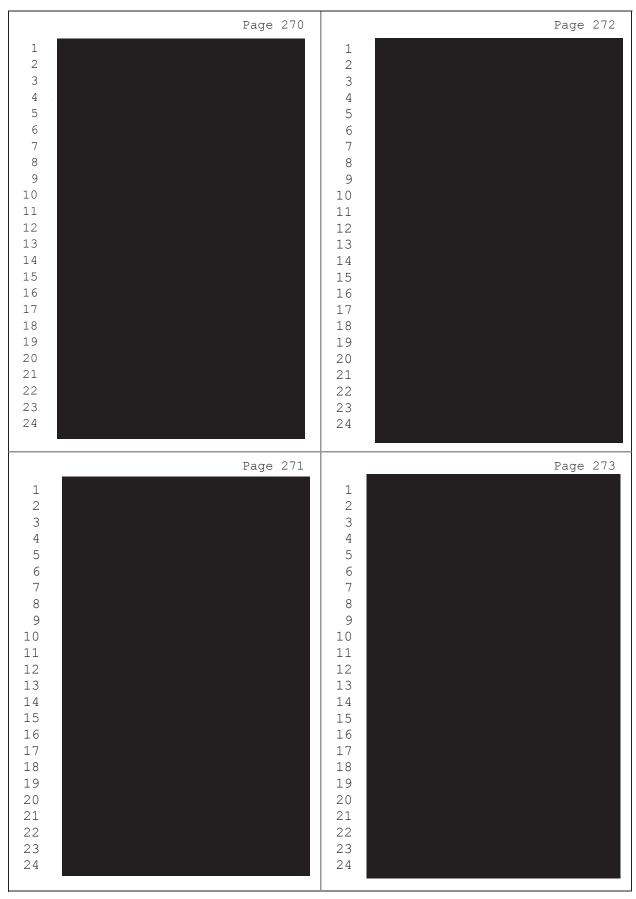
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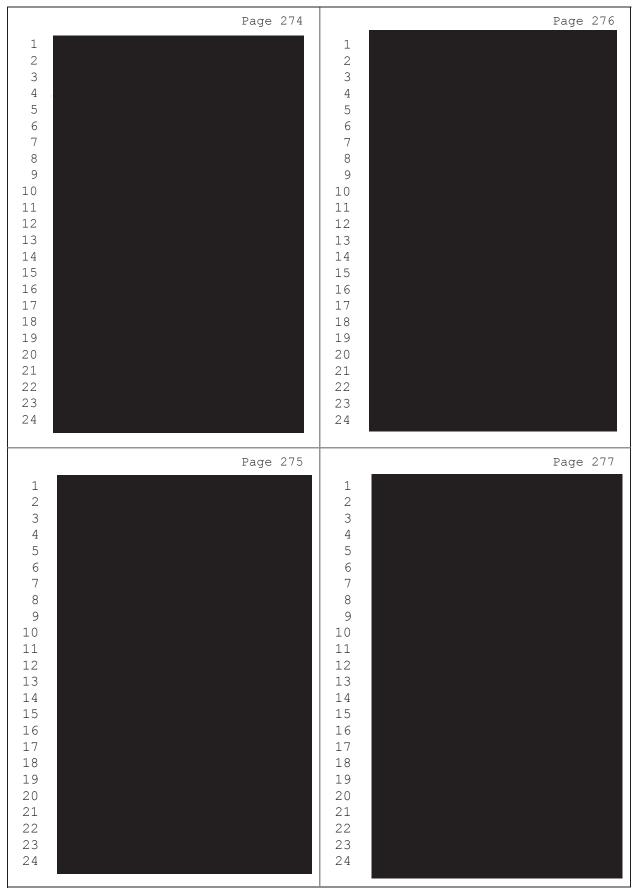
66 (Pages 258 to 261)



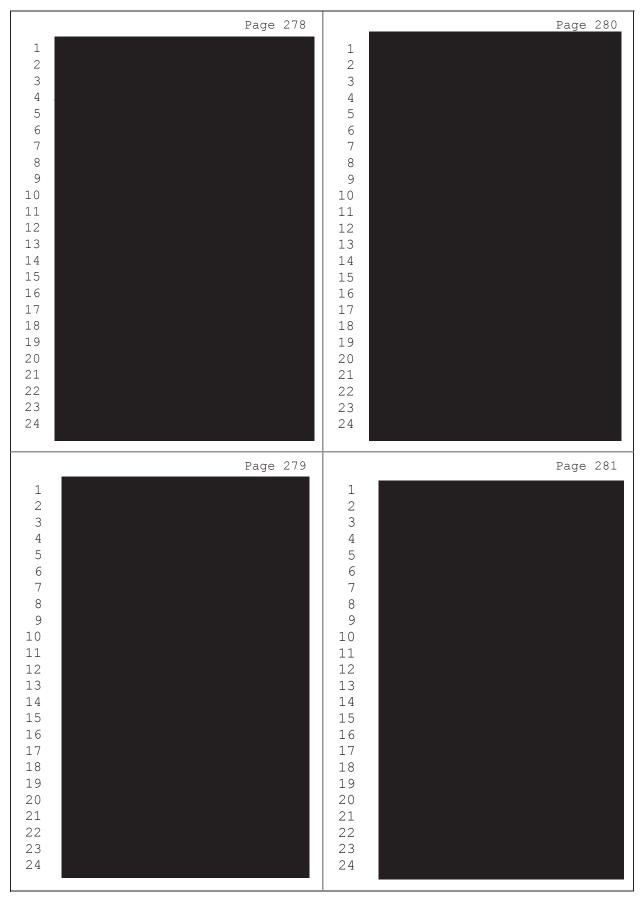
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Page 266
                                                                                         Page 268
                                                      1
 1
        refers further to drug poisoning
                                                                death rate per 100,000.
 2
                                                      2
                                                                    But we don't know death rate
        mortality, it doesn't specify what drugs
 3
        we're talking about.
                                                      3
                                                                from what.
 4
                                                            BY MS. AMINOLROAYA:
                Are these all drugs? Are
                                                      4
                                                      5
 5
        these opioids? Are these prescription
                                                                Q. And do you see more yellow
                                                      6
 6
        opioids? Are they -- does it include
                                                            and more orange and more red in 2012?
 7
        barbiturates, for example? I just don't
                                                      7
                                                                    MR. DAVIS: Objection to
 8
        know what this is.
                                                      8
                                                                form.
 9
                                                      9
            Q. So let's compare the 2001
                                                                    THE WITNESS: Well, strictly
                                                    10
10
        map to the 2012 map.
                                                                from a color perspective, the map
                                                                from 2001 has more blue on it and
11
                Would you agree there is a
                                                    11
12
        lot of blue in the 2001 map?
                                                    12
                                                                less red and vellow, as you just
13
                                                    13
                                                                stated, than the map from 2012.
            A. Yes.
14
                MR. DAVIS: Objection to
                                                    14
                                                                    But, again, what that refers
                                                                to and what the data is, is not
15
                                                    15
            form
                                                    16
                                                                clear from this. And I'm not
16
        BY MS. AMINOLROAYA:
17
                                                    17
                                                                familiar with it, so I don't want
            Q. And do you see less blue in
18
                                                    18
                                                                to speculate.
        the 2012 map?
19
                                                    19
                                                            BY MS. AMINOLROAYA:
                MR. DAVIS: Objection to
20
                                                    20
                                                                Q. And that's the same time you
            form.
                                                    21
                                                            were running the NIPC program, correct?
21
        BY MS. AMINOLROAYA:
22
                                                    22
                                                                    MR. DAVIS: Objection to
            Q. Page 14.
23
                                                    23
            A. And you asked me do I see
                                                                form
                                                    2.4
                                                                    THE WITNESS: The NIPC
24
        less --
                                    Page 267
                                                                                         Page 269
                                                     1
                                                               program was being conducted on
 1
            Q. Do you see less of the color
 2
        blue in the 2012 map?
                                                     2
                                                               appropriate pain management, which
 3
               MR. DAVIS: Objection to
                                                     3
                                                               included opioids but was not 100
                                                               percent focused on opioids. It
 4
                                                      4
            form.
                                                     5
                                                               included neuropathic pain and
 5
               THE WITNESS: Again, there
 6
            is -- there is less blue on this
                                                      6
                                                               chronic pain. And it did occur
                                                     7
                                                               during that time period.
 7
            map. But I don't -- still don't
                                                     8
                                                           BY MS. AMINOLROAYA:
 8
            understand particularly what
 9
            the -- what it is we're talking
                                                     9
                                                               O. Thank you.
10
                                                    10
            about here, what mortality data,
                                                    11
11
            what drug poisoning mortality data
12
            we're referencing.
                                                    12
                                                    13
13
        BY MS. AMINOLROAYA:
14
            Q. And the color bar on the
                                                    14
15
        right side here tells us that yellow
                                                    15
16
        means deaths are up from 2 to 14 per
                                                    16
        100,000 people. And red means that
                                                    17
17
        deaths are up from 2, for blue, to 26 or
                                                    18
18
                                                    19
        more per 100,000 people, correct?
19
               MR. DAVIS: Objection to
20
                                                    20
                                                    21
21
            form.
                                                    22
22
               THE WITNESS: Well, again, I
2.3
            can see what the legend on the map
                                                    23
                                                    24
24
            states, estimated age-adjusted
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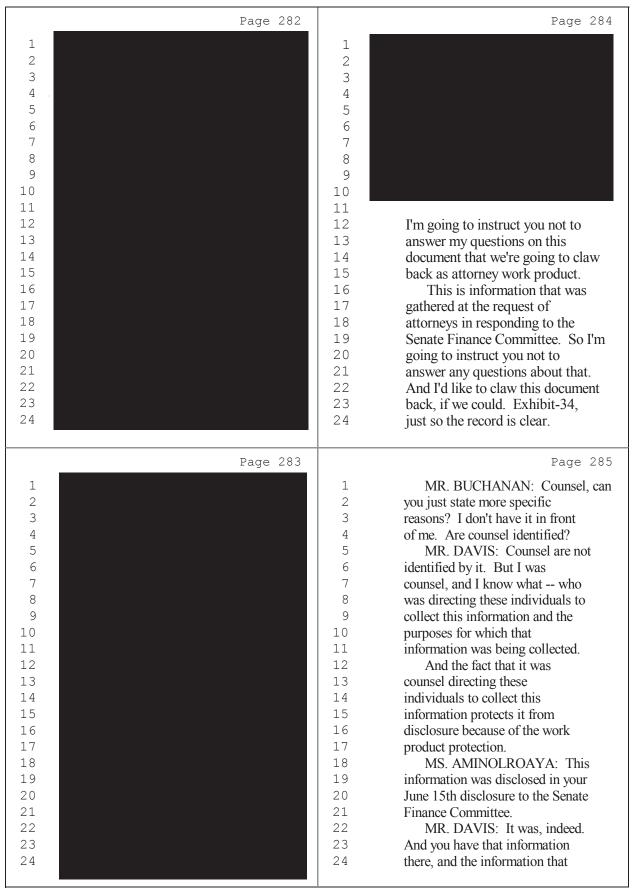
69 (Pages 270 to 273)



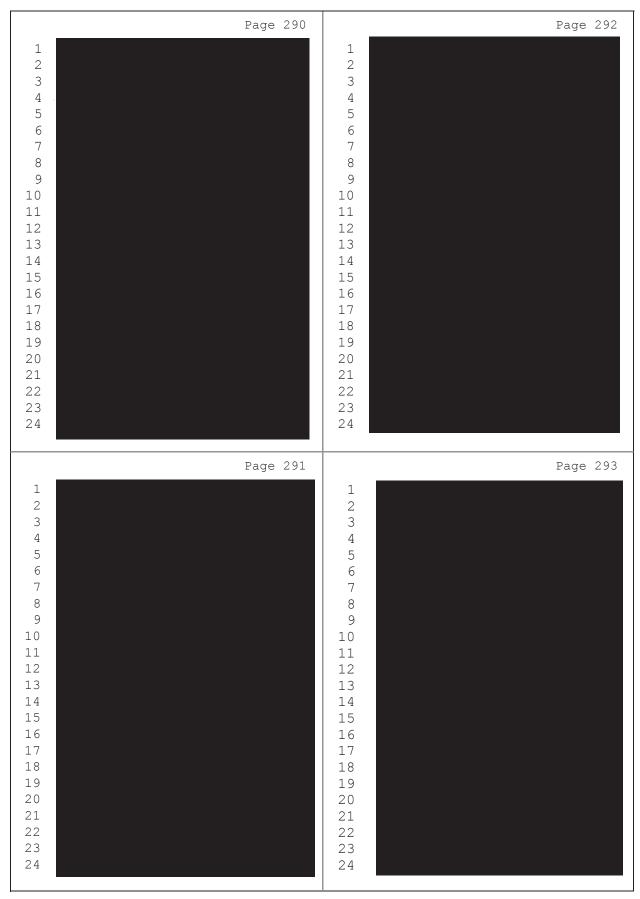
70 (Pages 274 to 277)



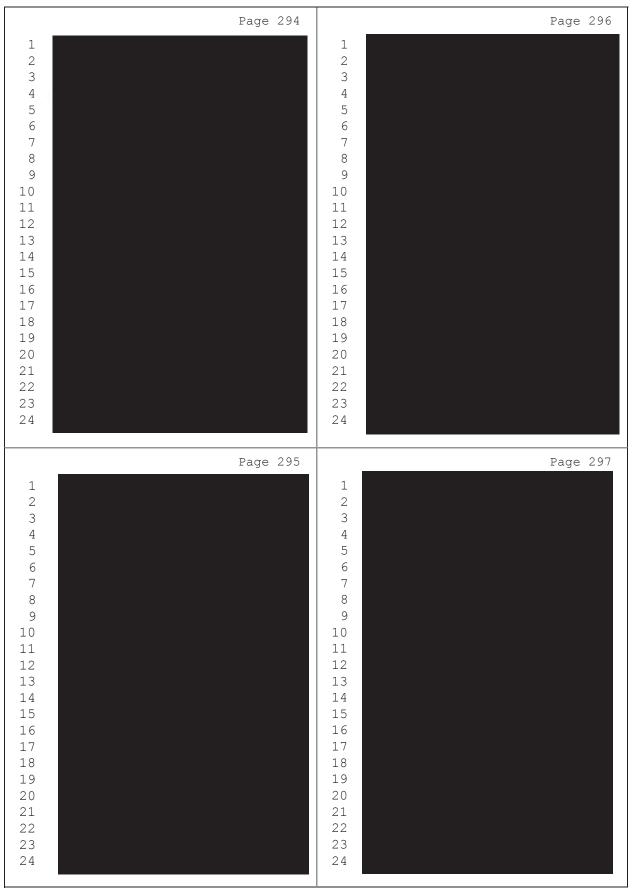
71 (Pages 278 to 281)



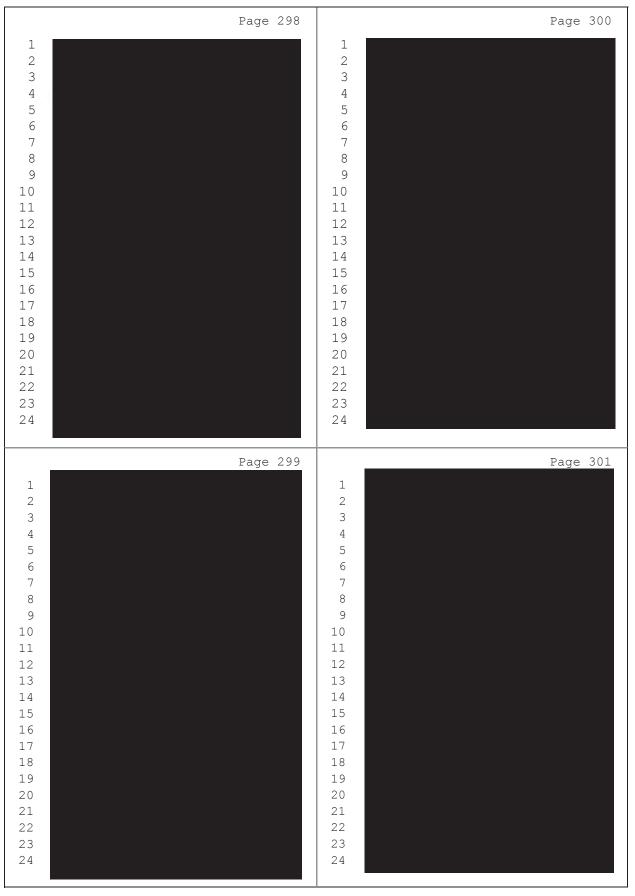
	Page 286		Page 288
1	was disclosed is fine. But the	1	MS. AMINOLROAYA: She
2	information as collected by these	2	testified before
3	individuals specifically here, I	3	MR. DAVIS: Ms. Kitlinski's
4 .	don't know if there are	4	work collecting the information
5	differences, but this was	5	that was provided to the Senate
6	information provided collected	6	Finance Committee was directed by
7	by these individuals and provided	7	attorneys, provided to attorneys
8	to attorneys so the attorneys	8	so they could provide legal advice
9	could provide legal advice to the	9	to the company.
10	company, and is, therefore, work	10	MS. AMINOLROAYA: That's the
11	product.	11	same as Ms. Kitlinski gathering
12	MR. BUCHANAN: I'm not sure	12	documents subject to advice that
13	how it couldn't be a waiver, if it	13	she needed to respond to a
14		14	subpoena.
	was provided to the Senate as you	15	
15 16	just said.	16	MR. DAVIS: You asked the specifics of what she was
	MR. DAVIS: I mean, if it's	1	1
17	exactly the same as what we	17	gathering. That's not the same as
18	provided to the Senate, perhaps.	18	her gathering documents to respond
19	But I don't want to sit	19	to a subpoena.
20	here we can sit here and go	20	I don't think she that
21	through it if you want. I don't	21	wasn't done so we could provide
22	know if this is exactly what we	22	legal advice to the company. That
23	provided to the Senate or if there	23	was done to be responsive to the
24	are any changes.	24	subpoena you sent her.
2	can take a break in a moment.	2	
4 5 6 7 8 9 10	Maybe you can just take a look at it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not	3 4 5 6 7 8 9 10	
4 5 6 7 8 9 10 11	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial. We'll agree it's not a subject matter. MR. DAVIS: What's that? MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.	3 4 5 6 7 8 9 10 11	
4 5 6 7 8 9 10 11 12 13	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take	3 4 5 6 7 8 9 10 11 12 13	
4 5 6 7 8 9 10 11 12 13 14	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial. We'll agree it's not a subject matter. MR. DAVIS: What's that? MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver. MR. DAVIS: Fair. I'll take a look at it when we're on a	3 4 5 6 7 8 9 10 11 12 13 14	
4 5 6 7 8 9 10 11 12 13 14 15	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.	3 4 5 6 7 8 9 10 11 12 13 14 15	
4 5 6 7 8 9 10 11 12 13 14 15 16	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:	3 4 5 6 7 8 9 10 11 12 13 14 15 16	
4 5 6 7 8 9 10 11 12 13 14 15 16 17	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had responsibility for identifying some of	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had responsibility for identifying some of the information that went into the Senate	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had responsibility for identifying some of	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had responsibility for identifying some of the information that went into the Senate	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had responsibility for identifying some of the information that went into the Senate Finance Committee?  MR. DAVIS: I'm going to	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had responsibility for identifying some of the information that went into the Senate Finance Committee?  MR. DAVIS: I'm going to object to that as well as	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it, so we don't have to needlessly have a privilege challenge. It might not be that controversial.  We'll agree it's not a subject matter.  MR. DAVIS: What's that?  MR. BUCHANAN: We'll agree that examination on this would not be a broader waiver.  MR. DAVIS: Fair. I'll take a look at it when we're on a break.  BY MS. AMINOLROAYA:  Q. So, Ms. Kitlinski, you had responsibility for identifying some of the information that went into the Senate Finance Committee?  MR. DAVIS: I'm going to	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	



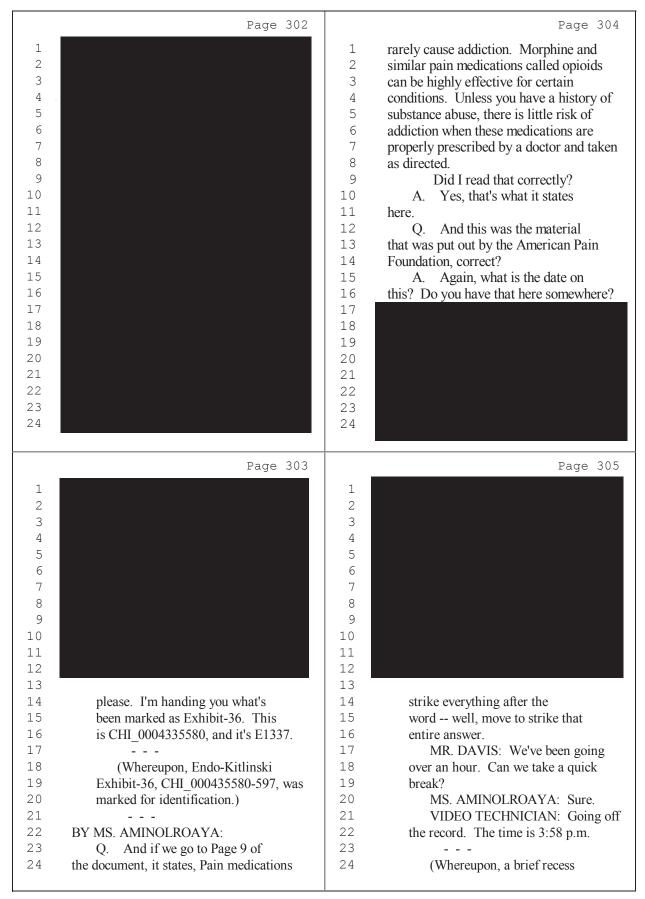
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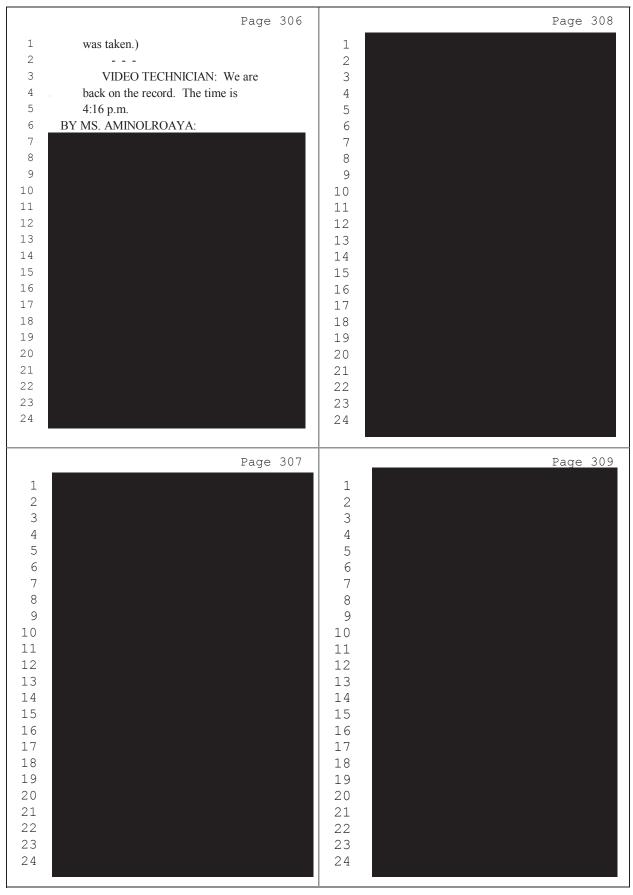


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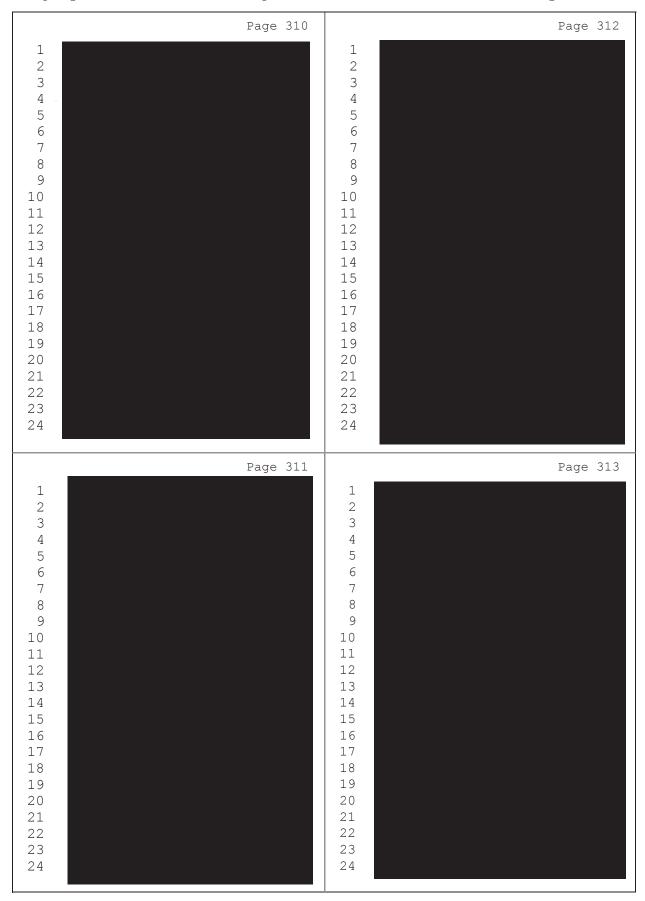


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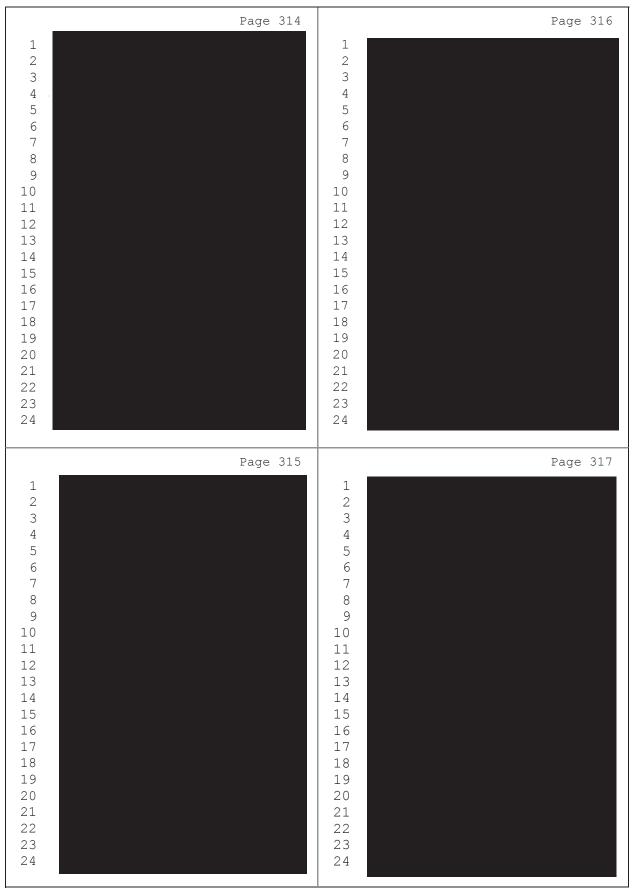




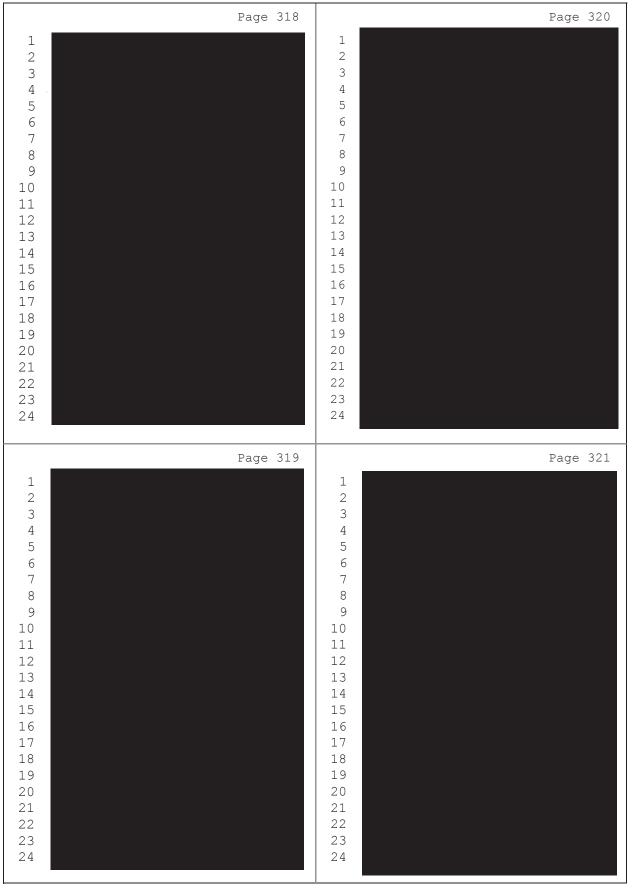
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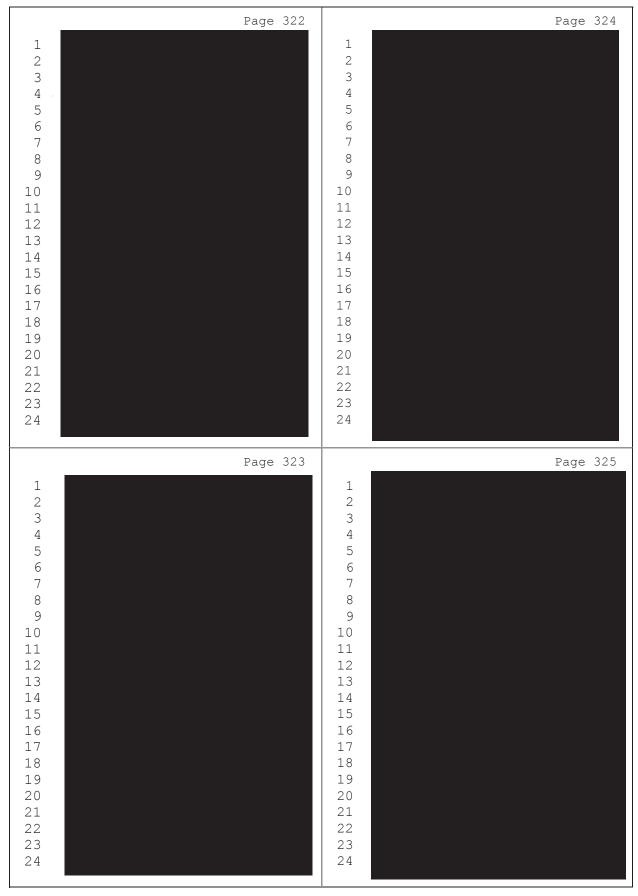
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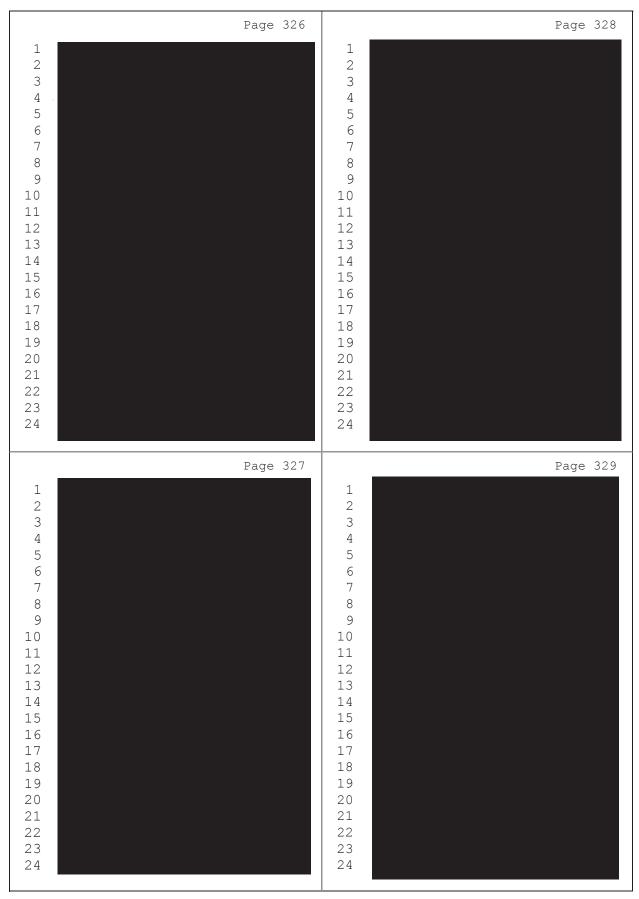
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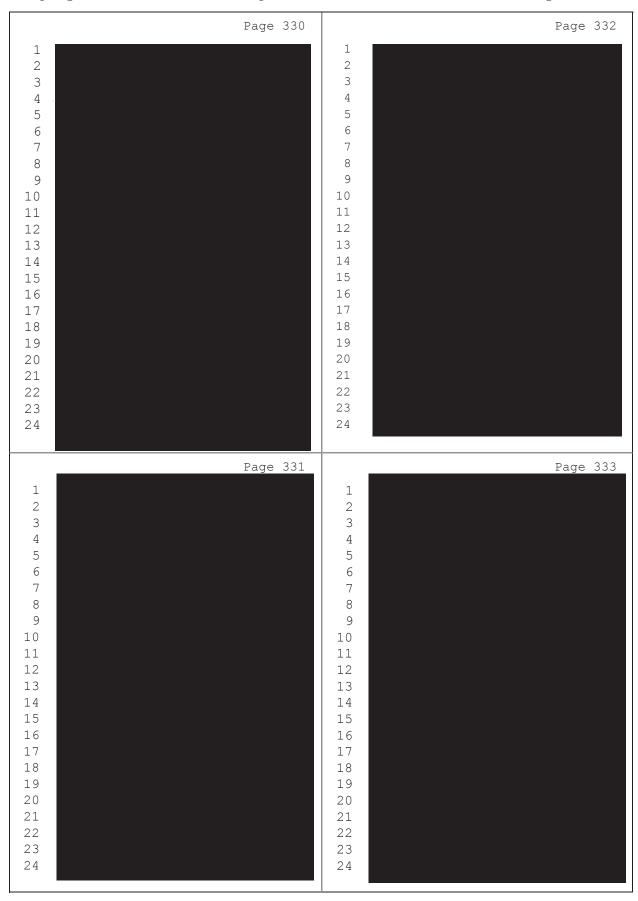
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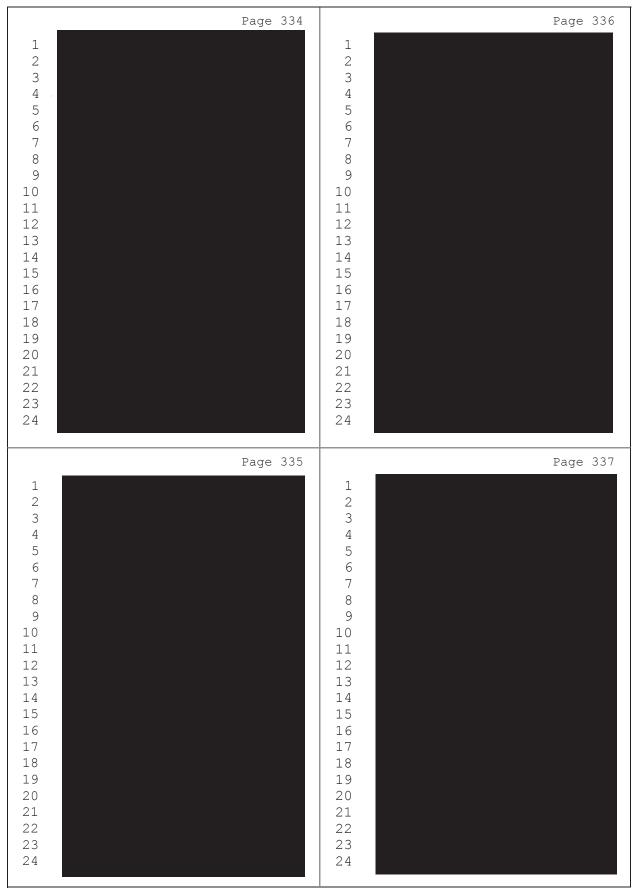
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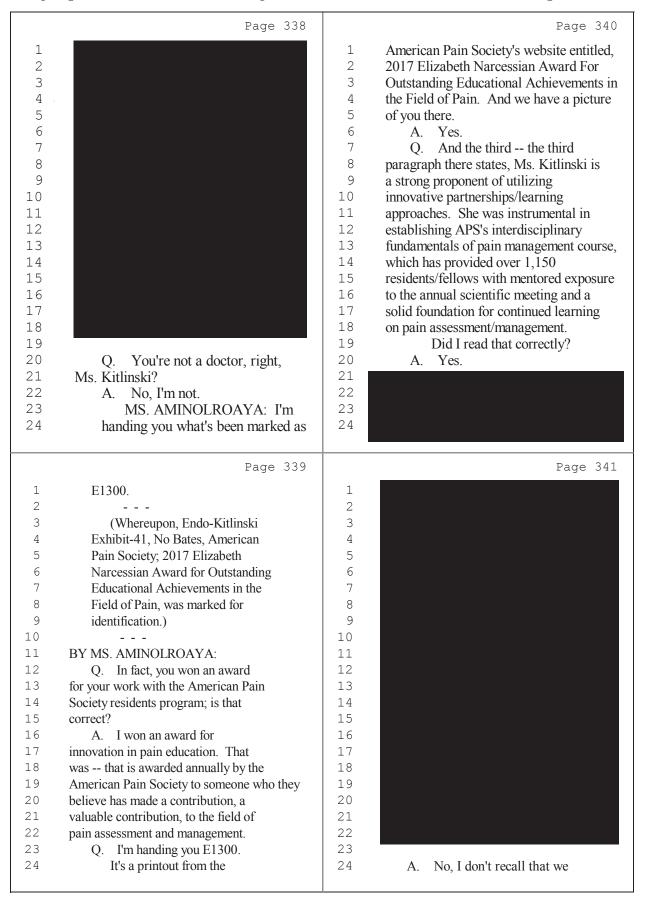
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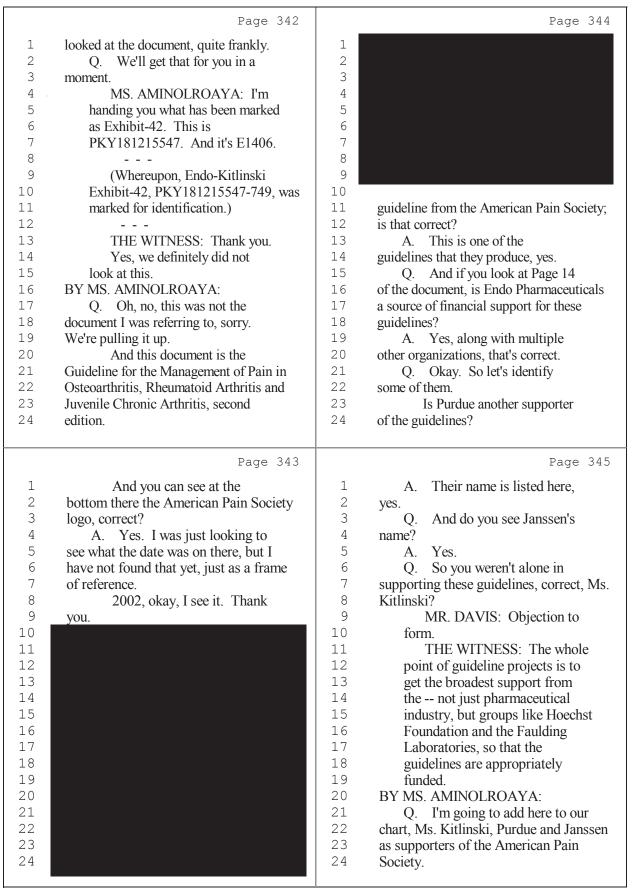
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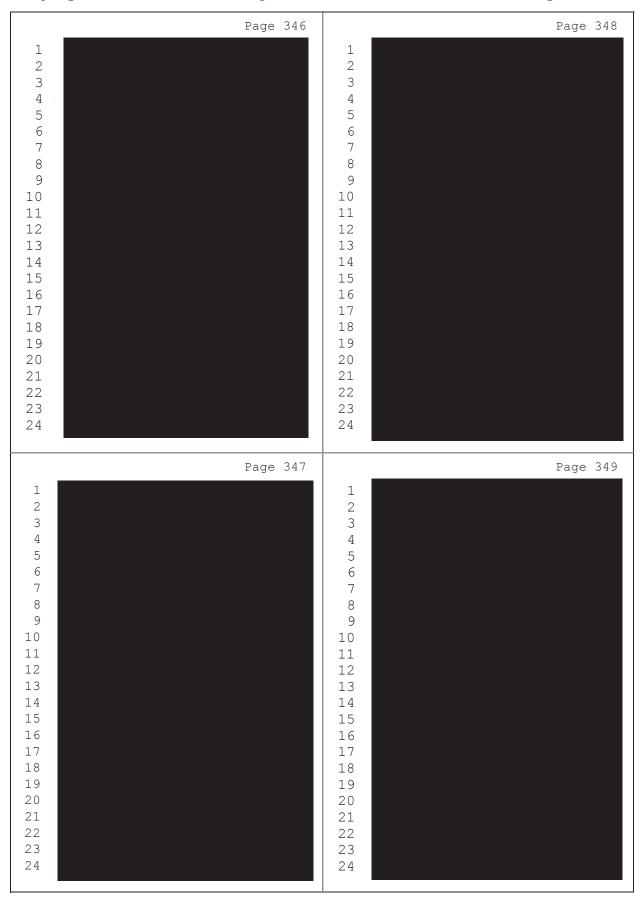


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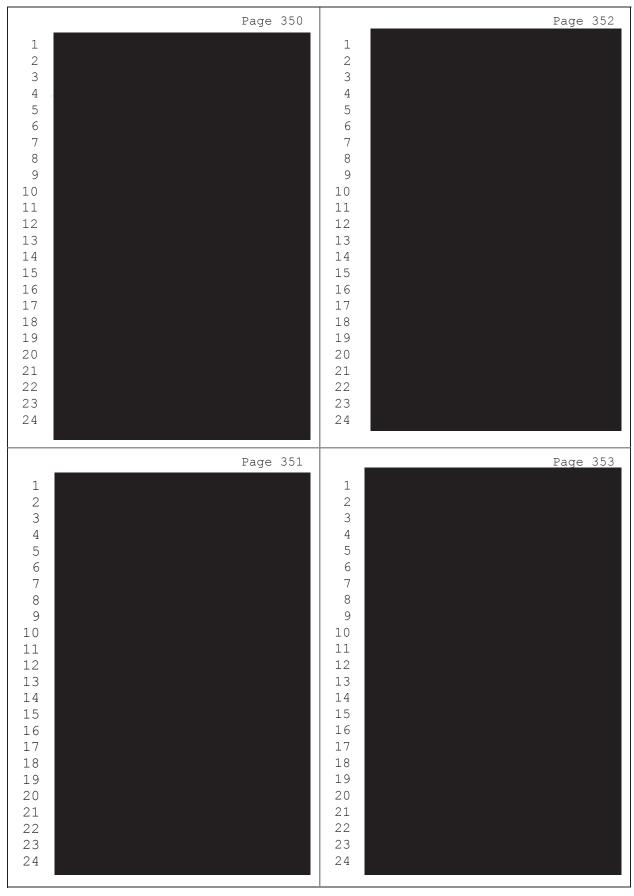


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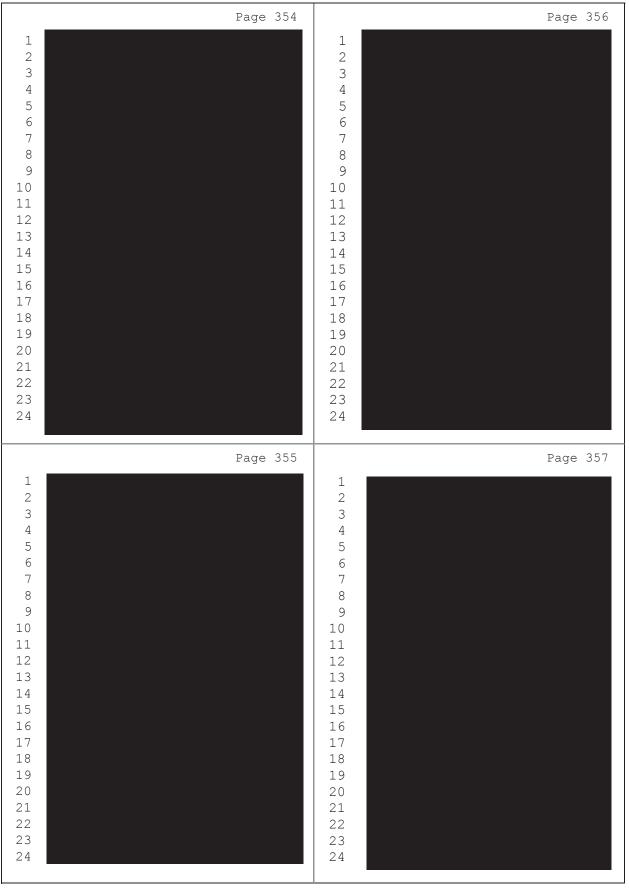




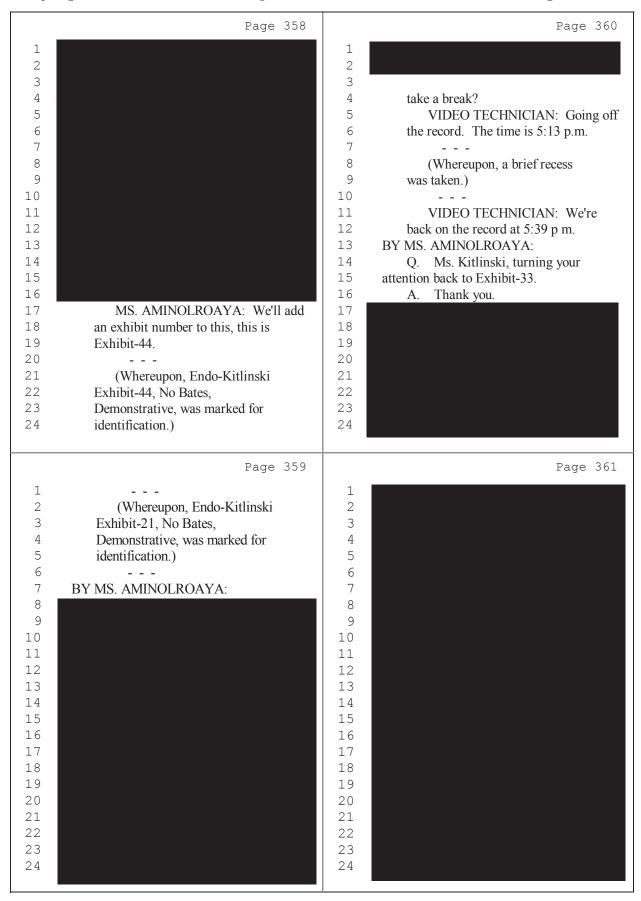
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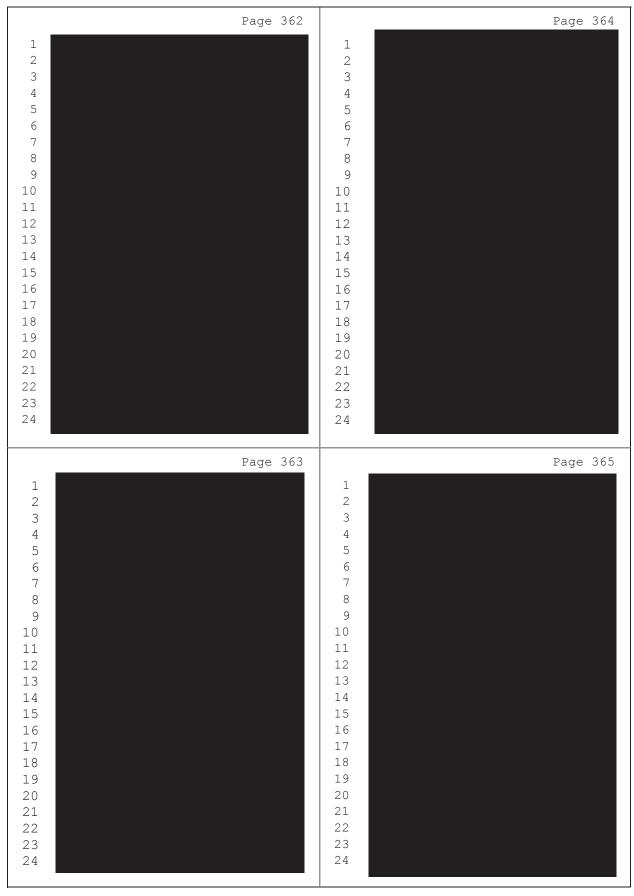
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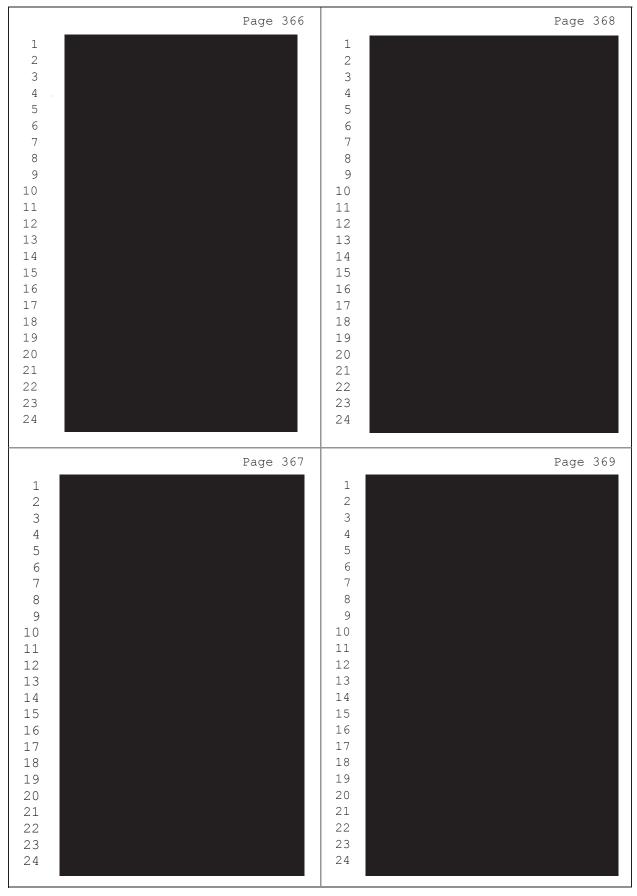
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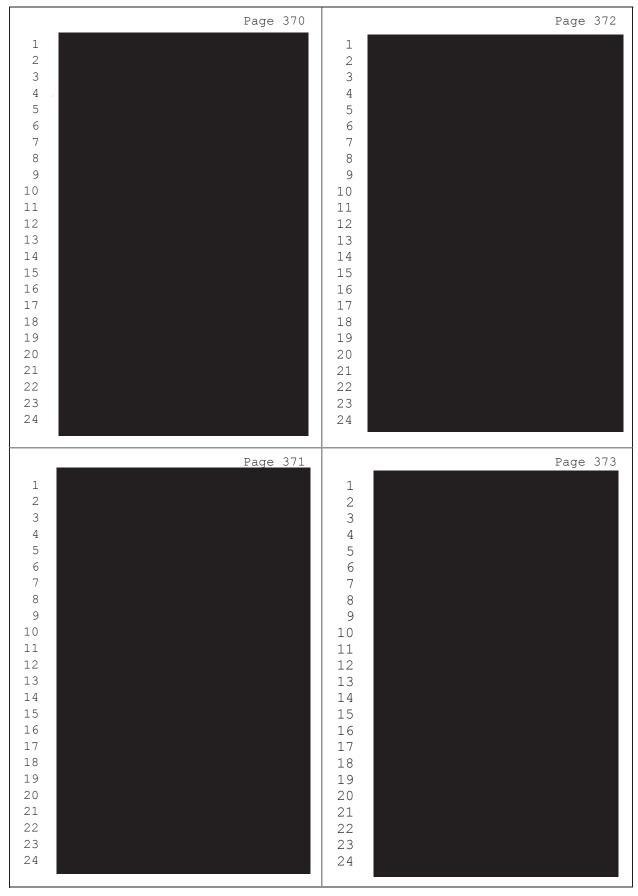
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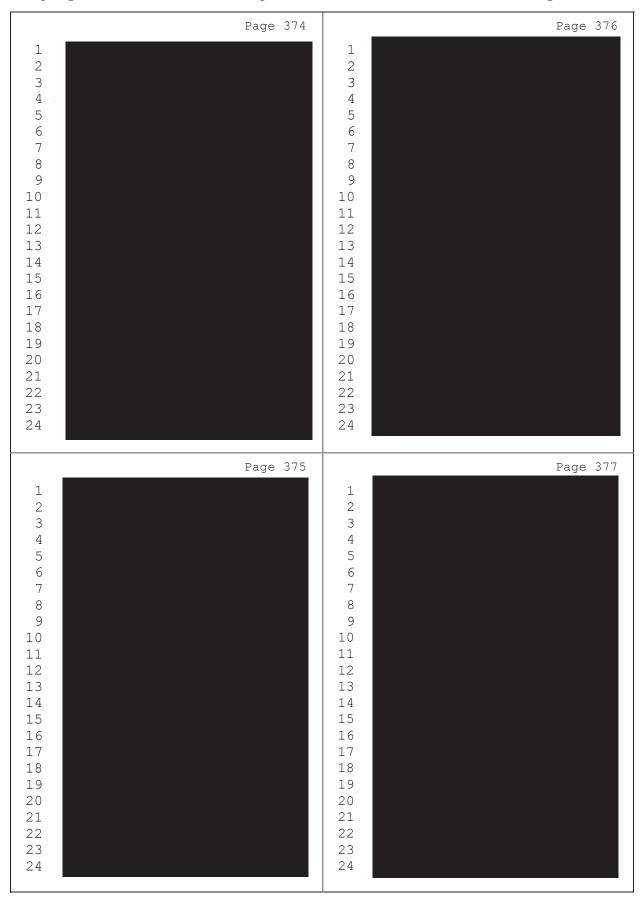
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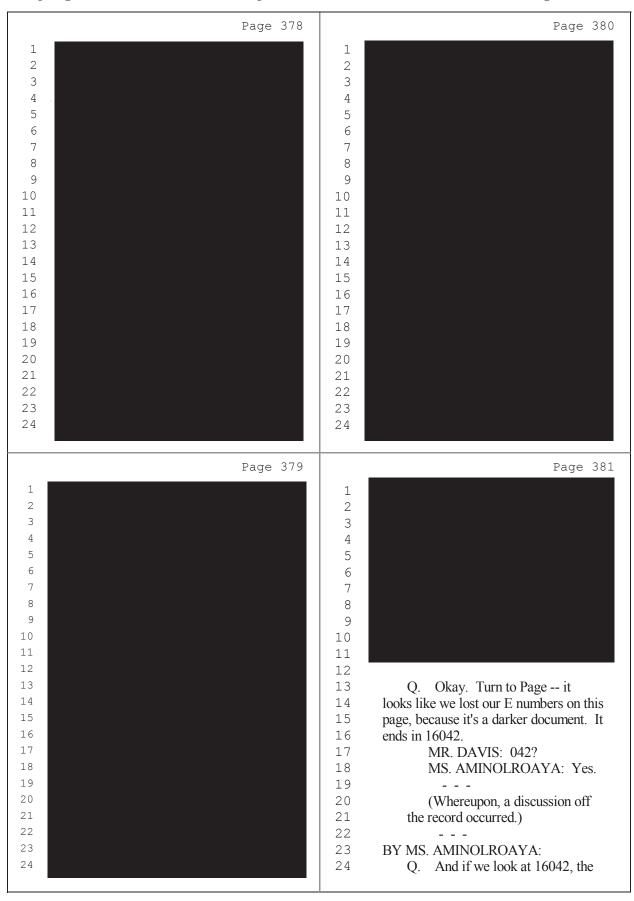
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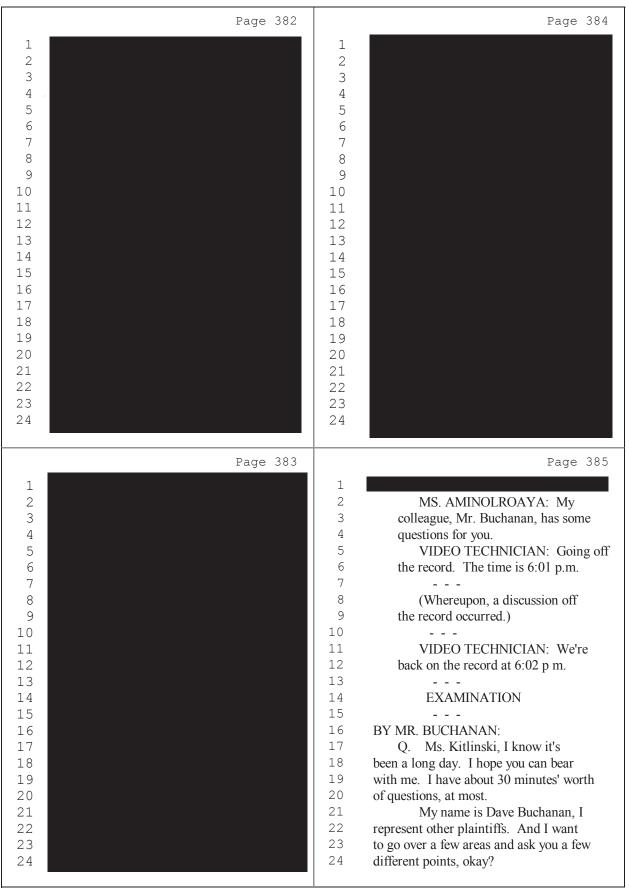
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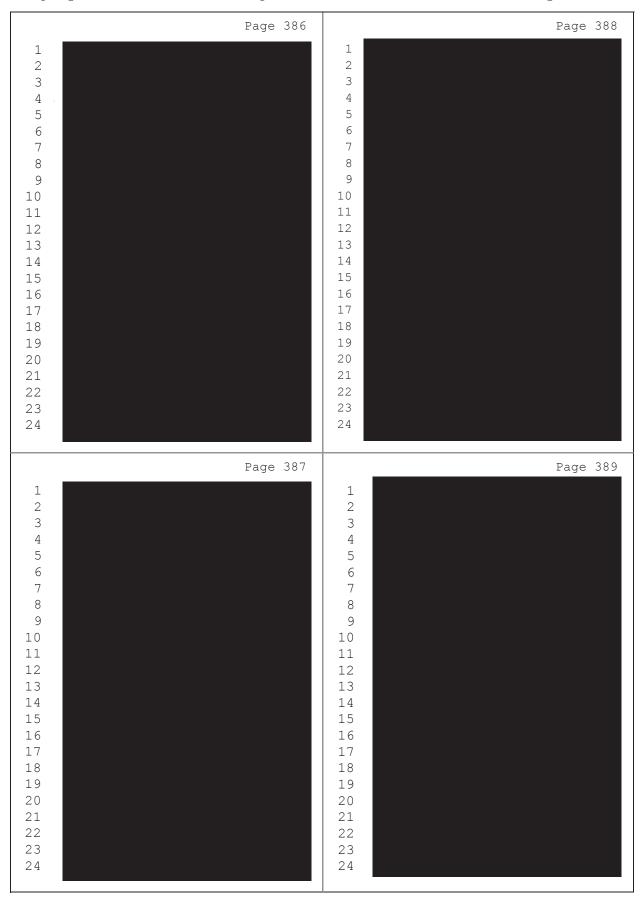
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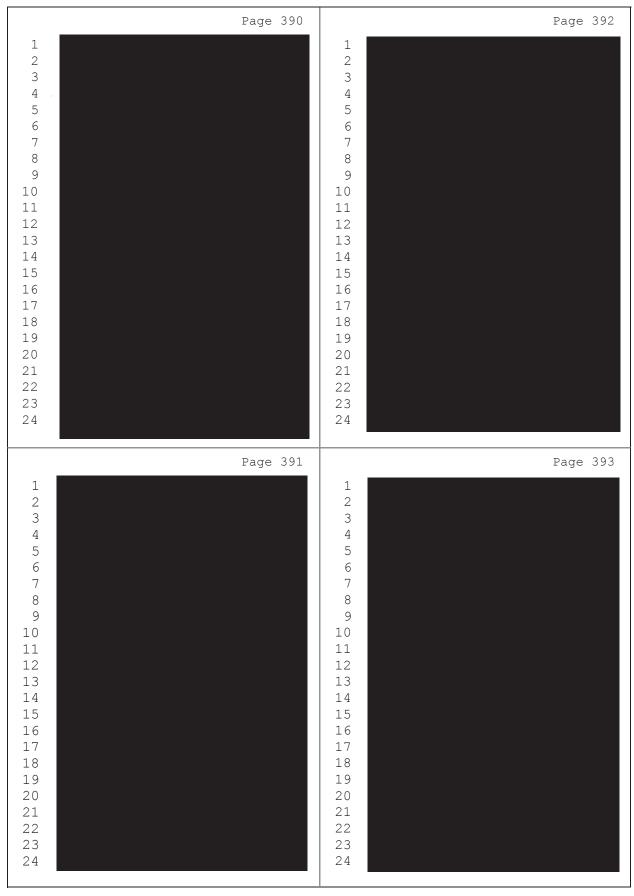
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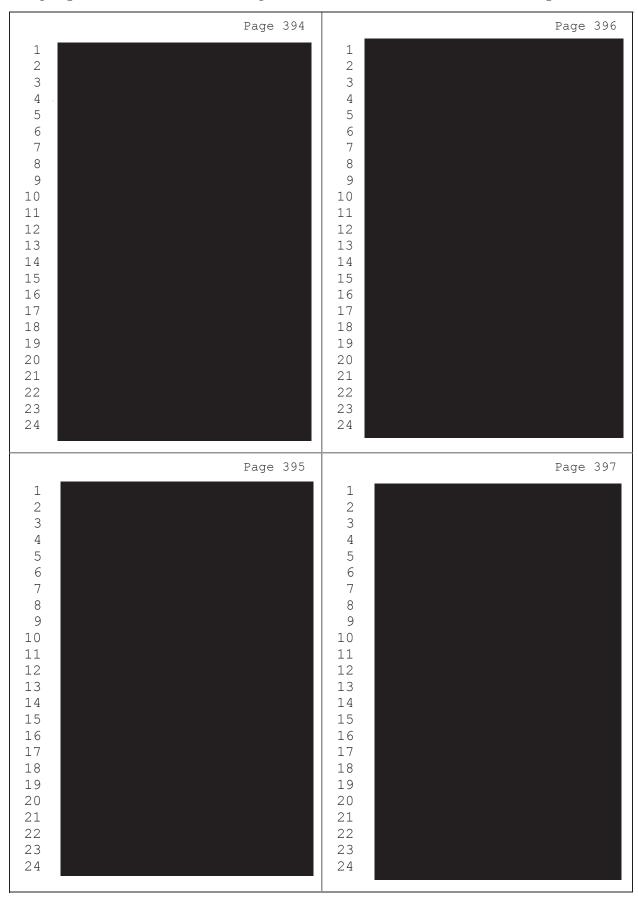
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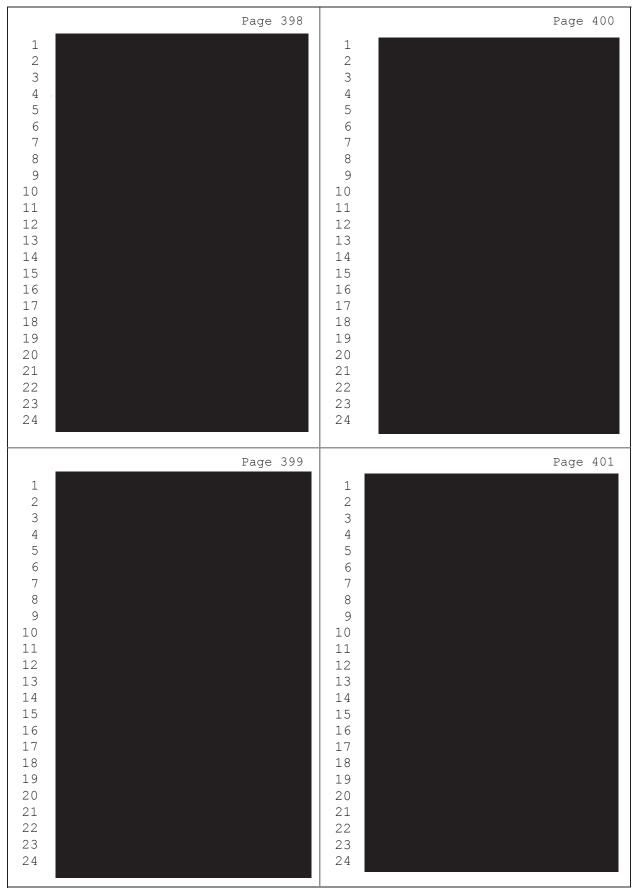
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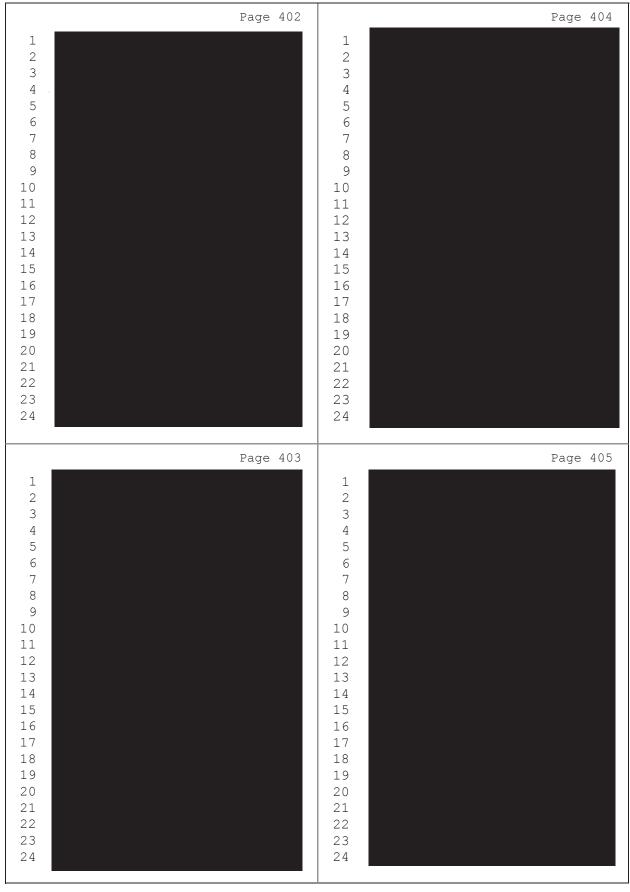
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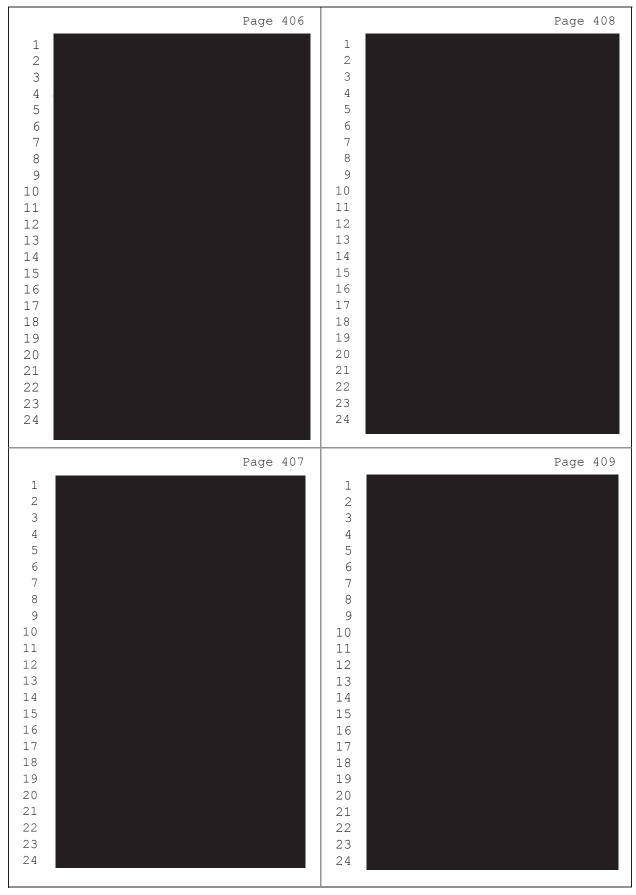
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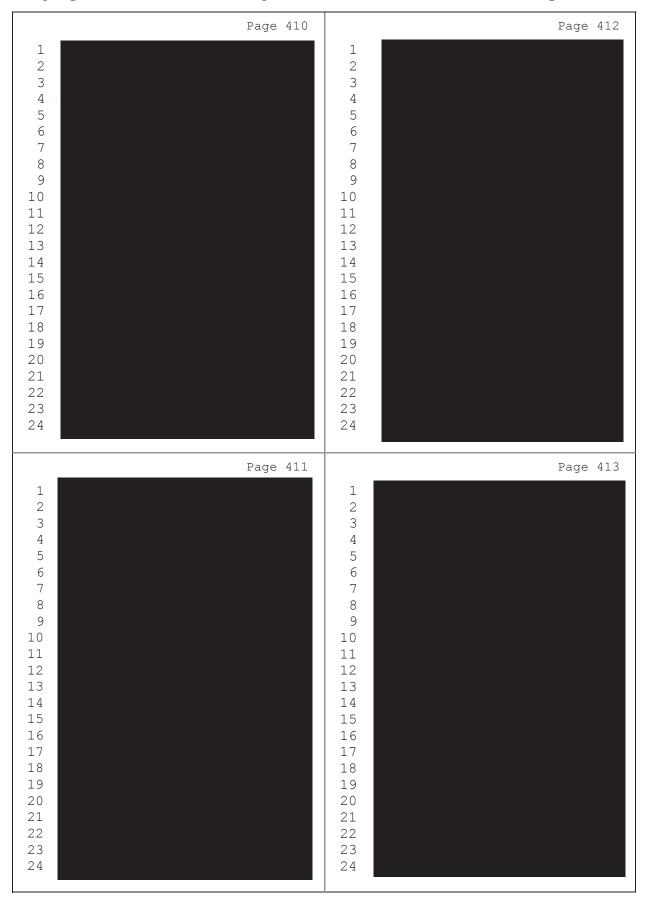
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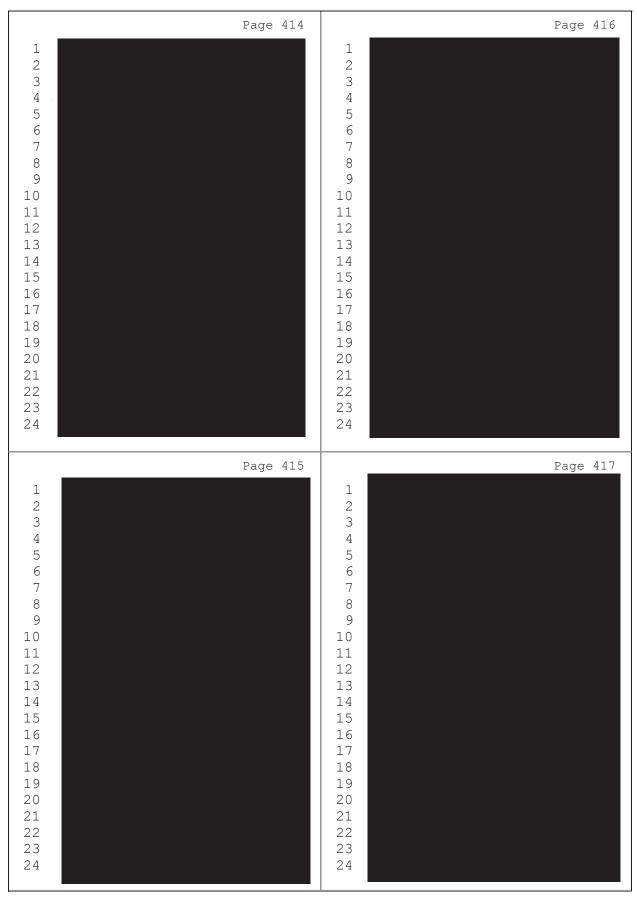
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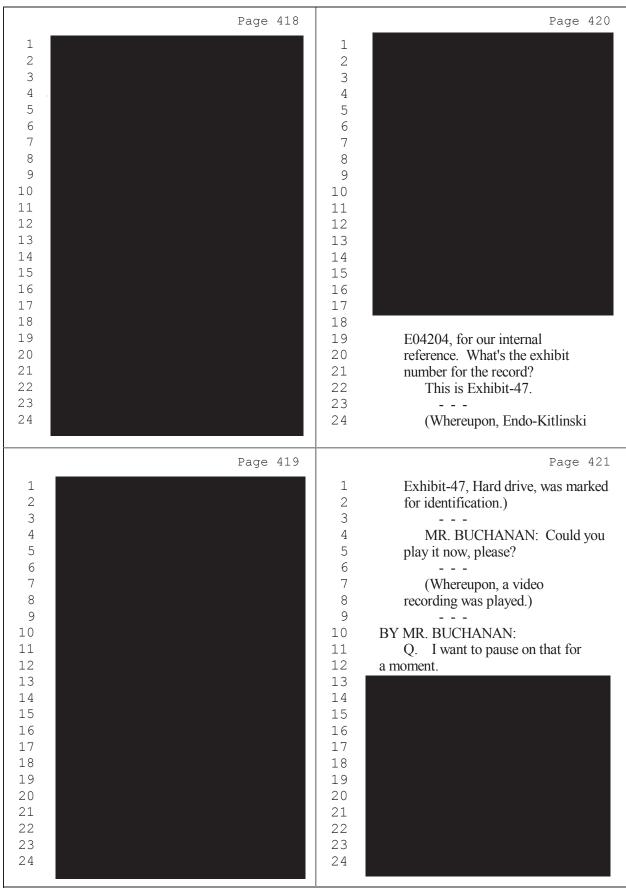
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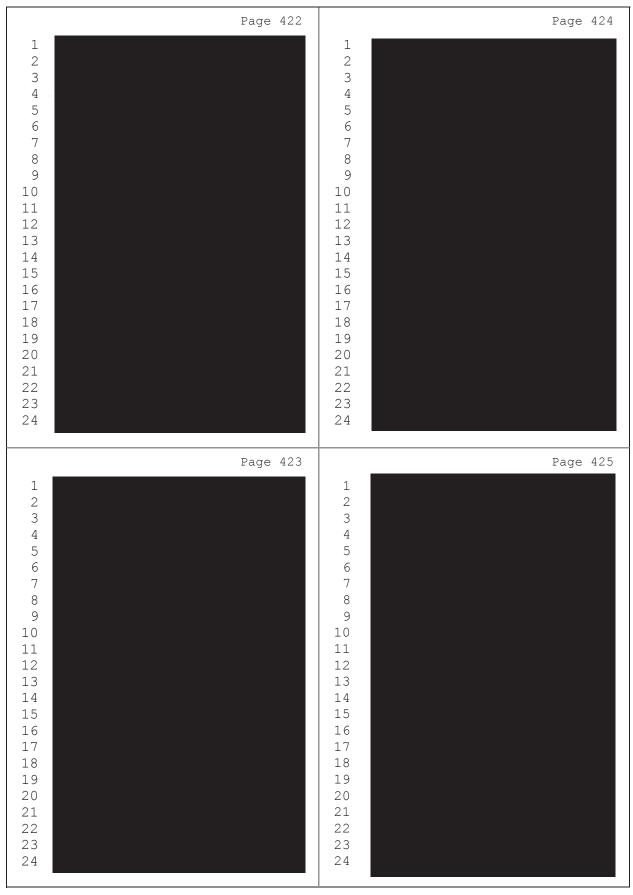
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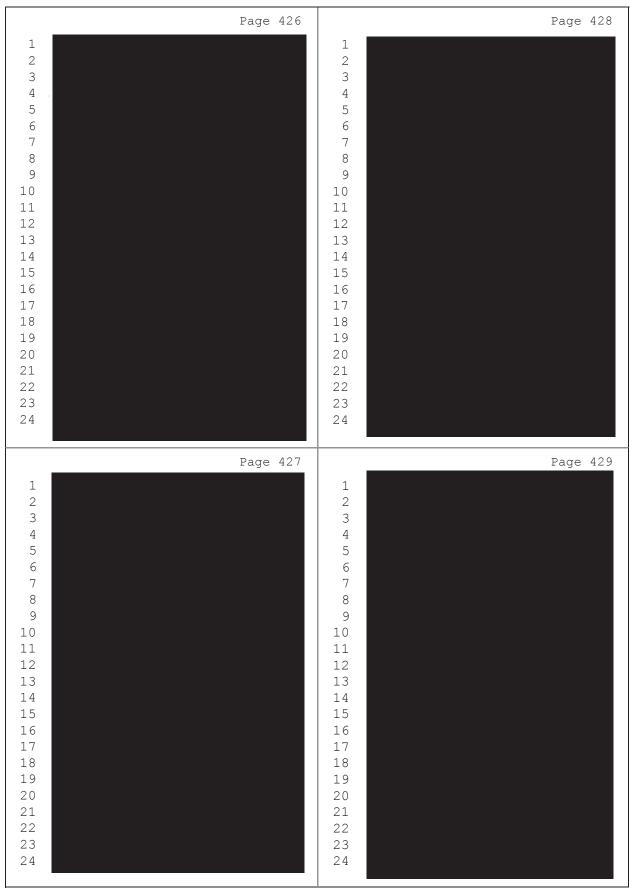
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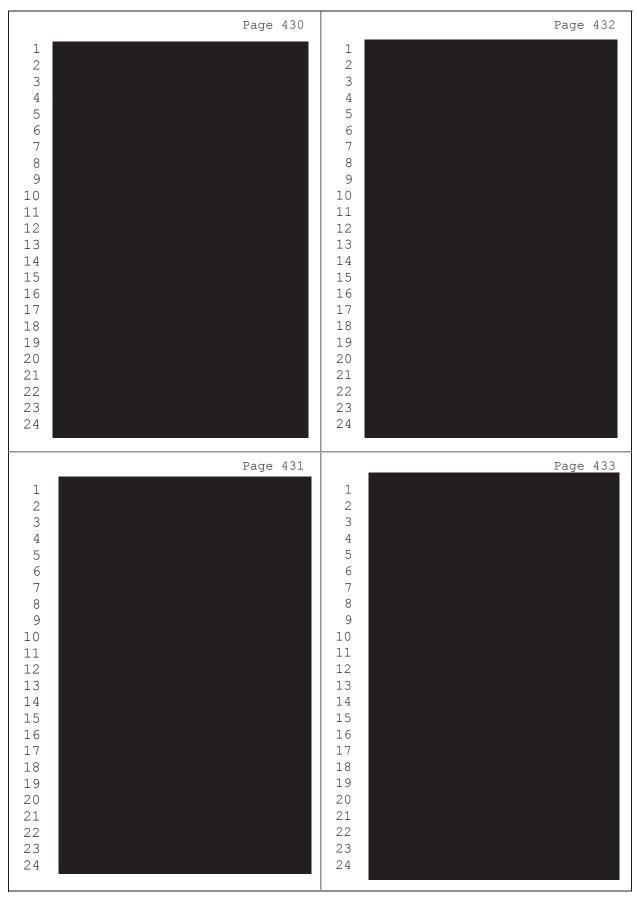
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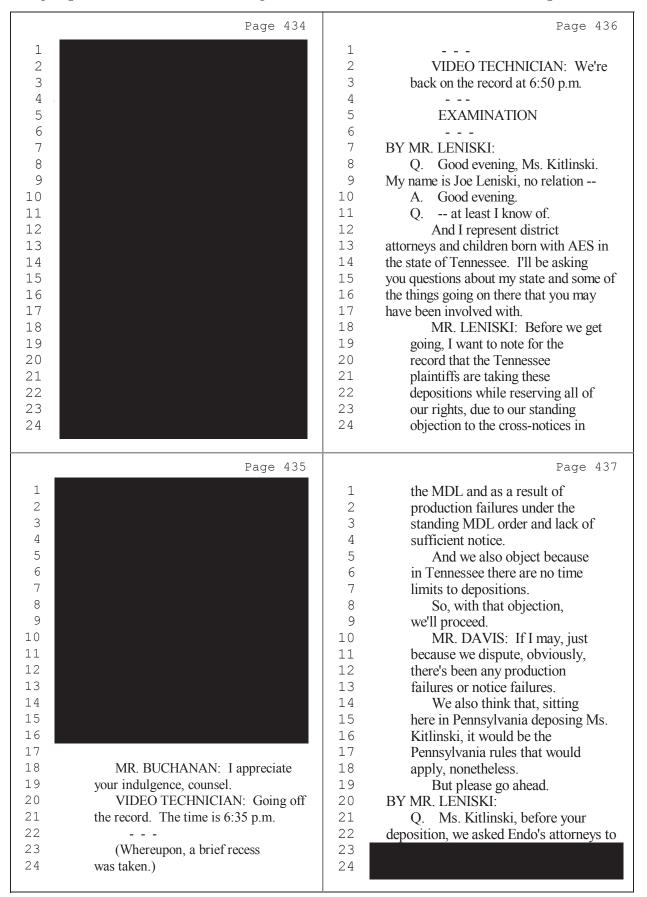
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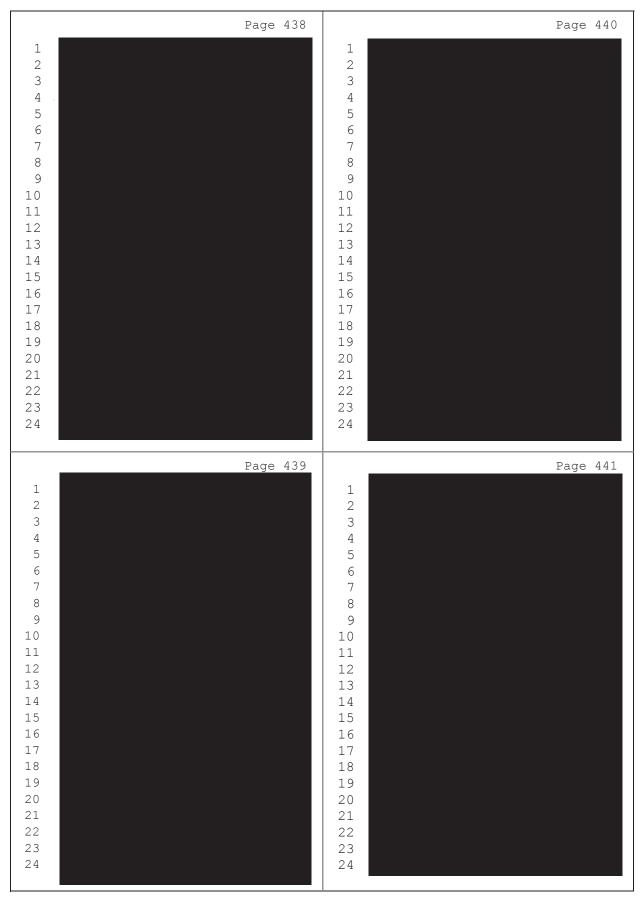


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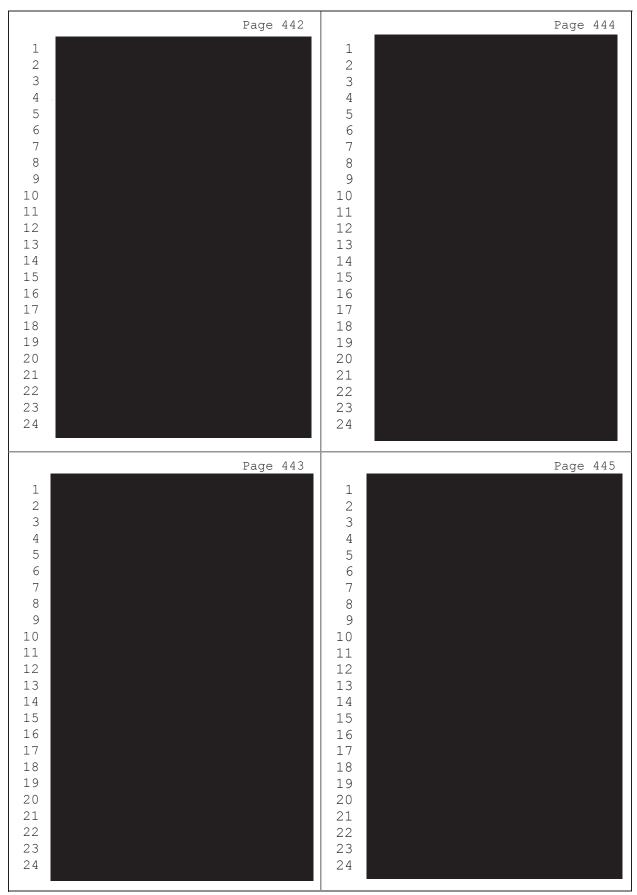


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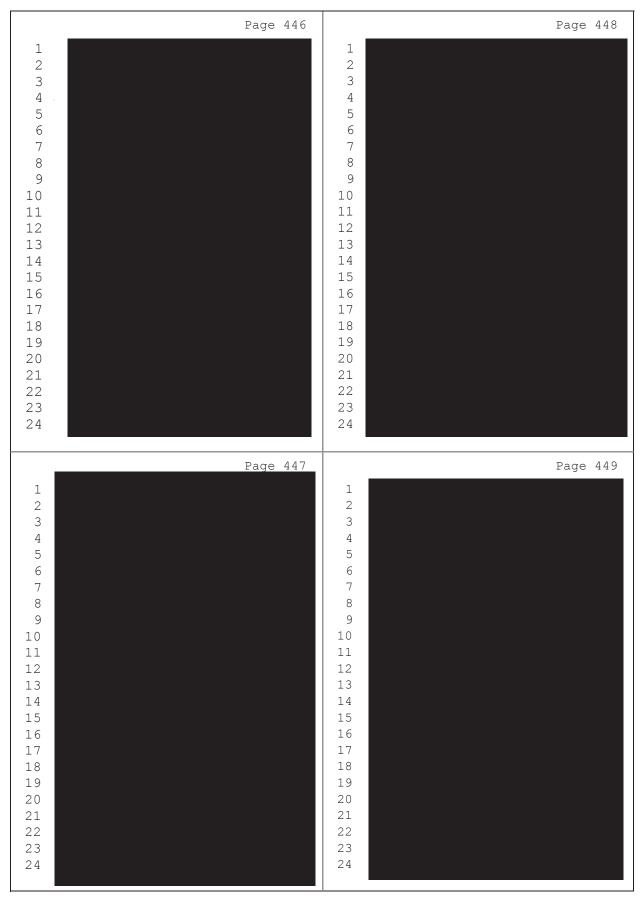




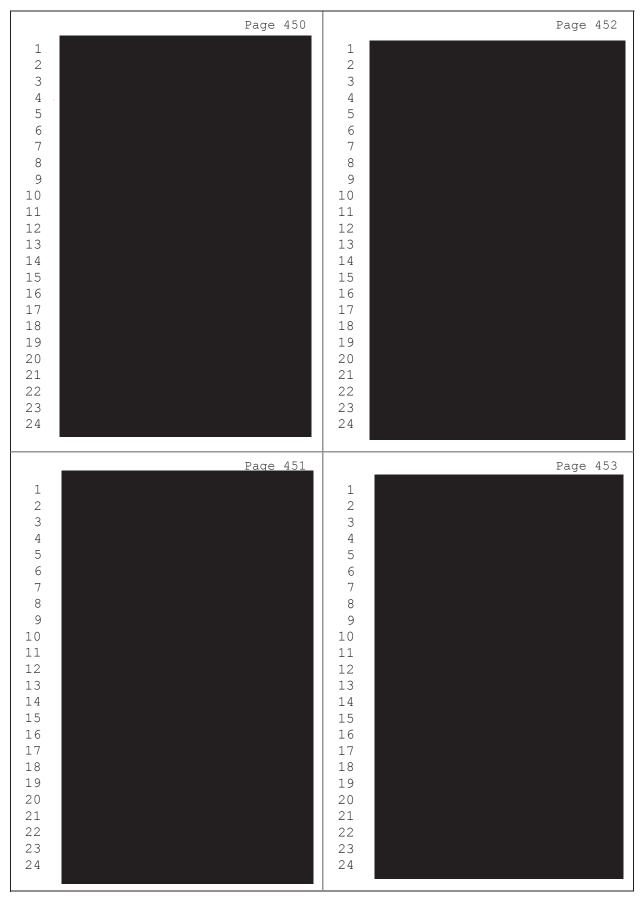
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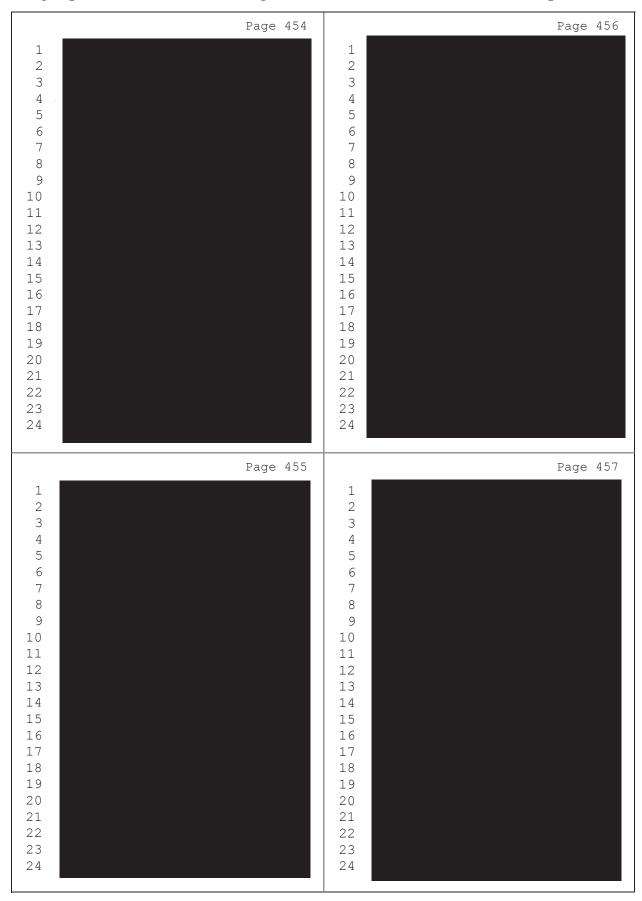
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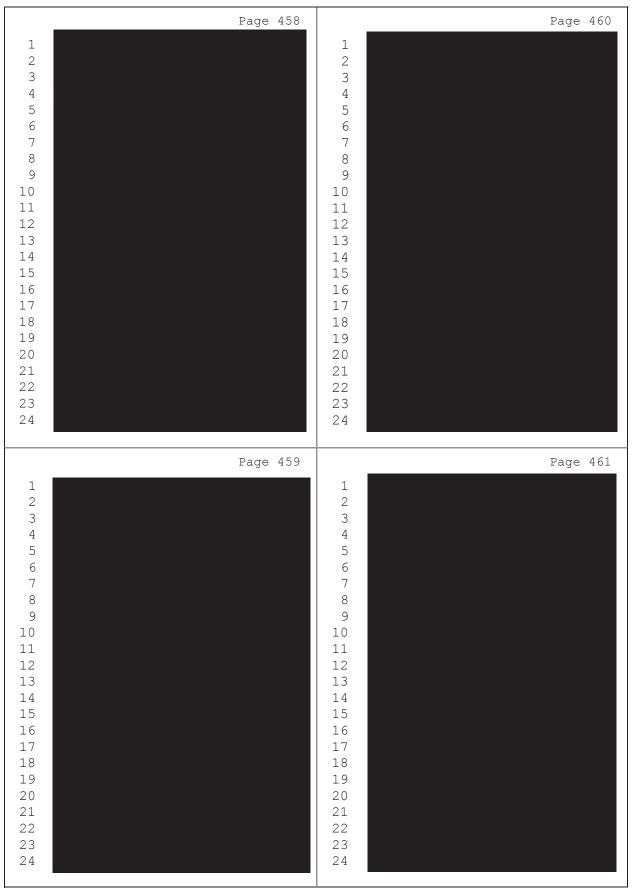
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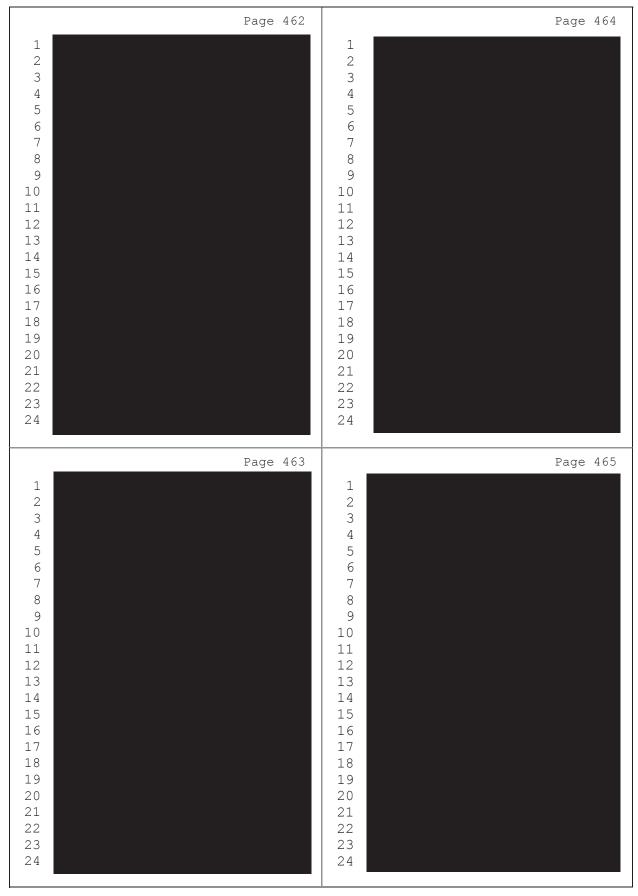
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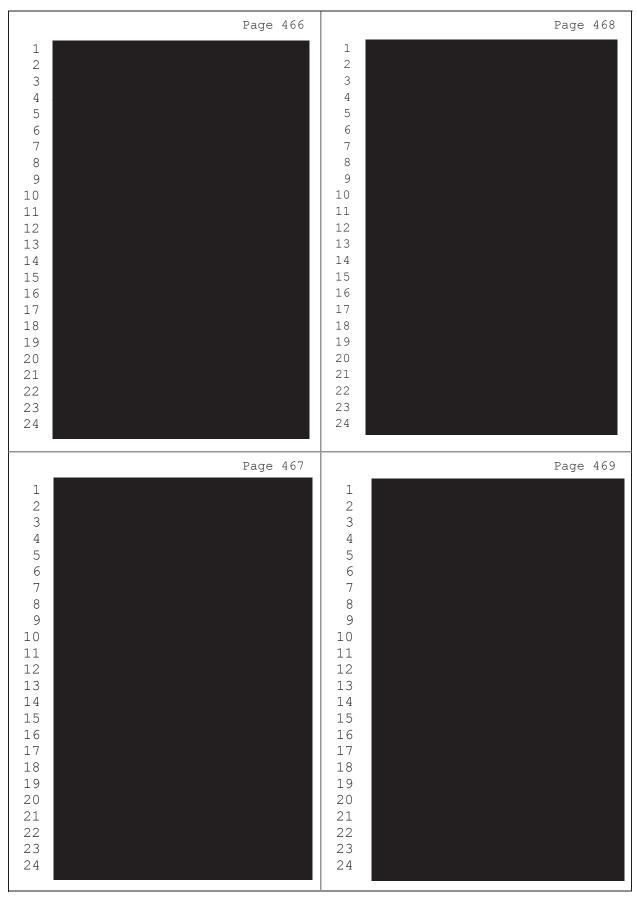
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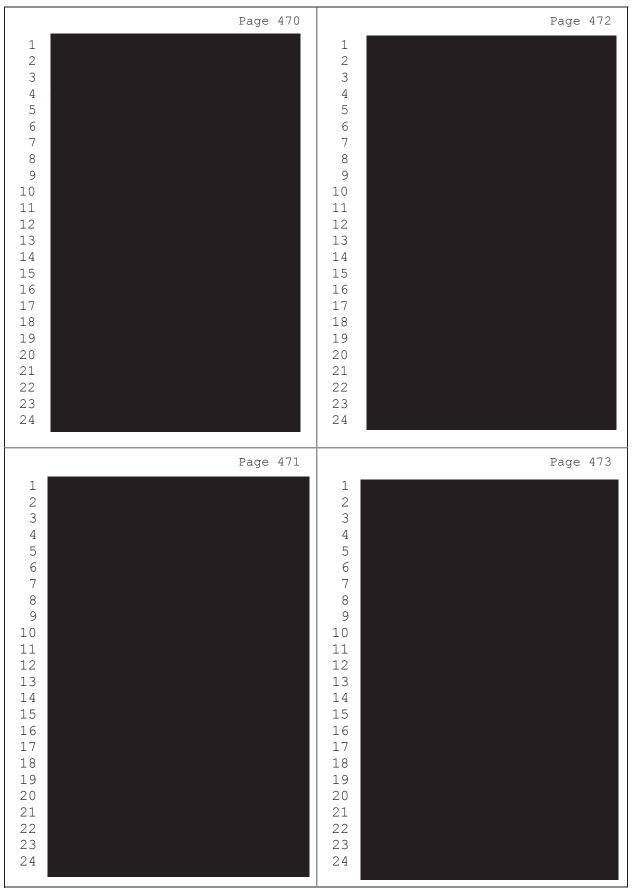
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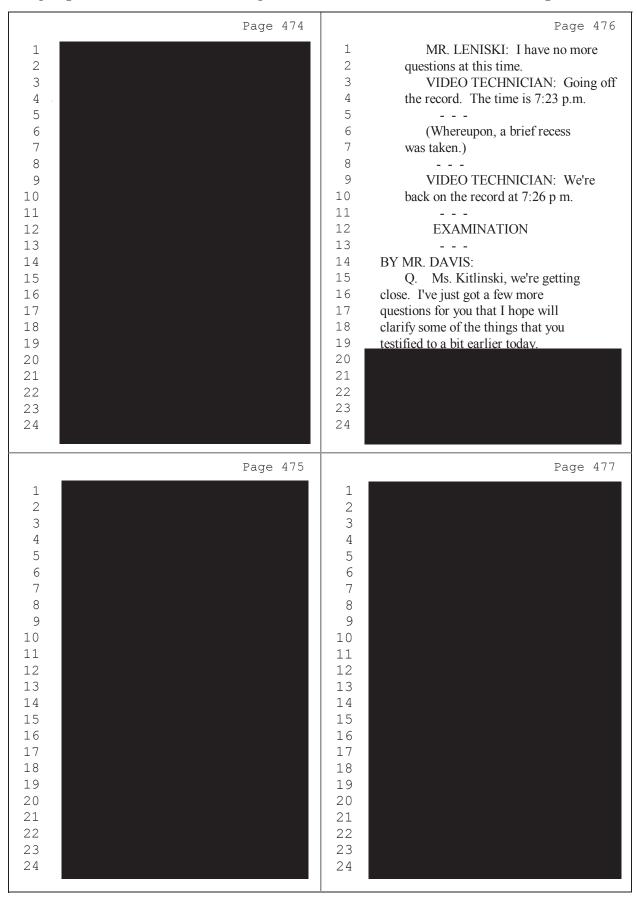
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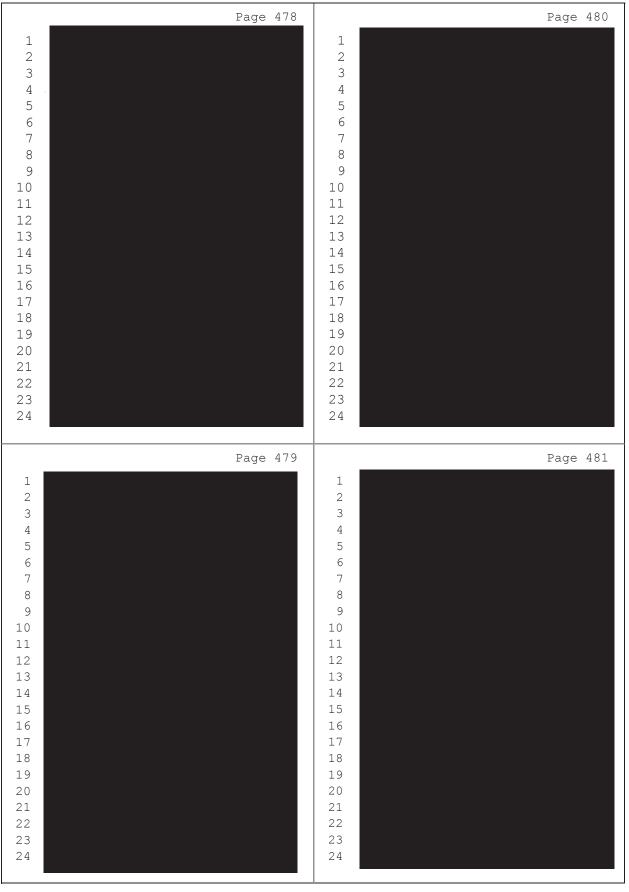
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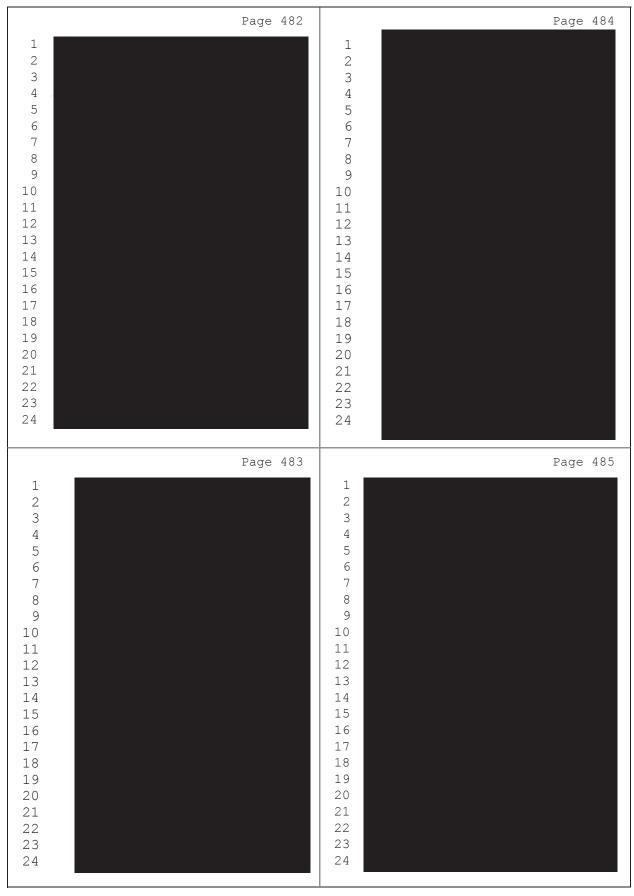
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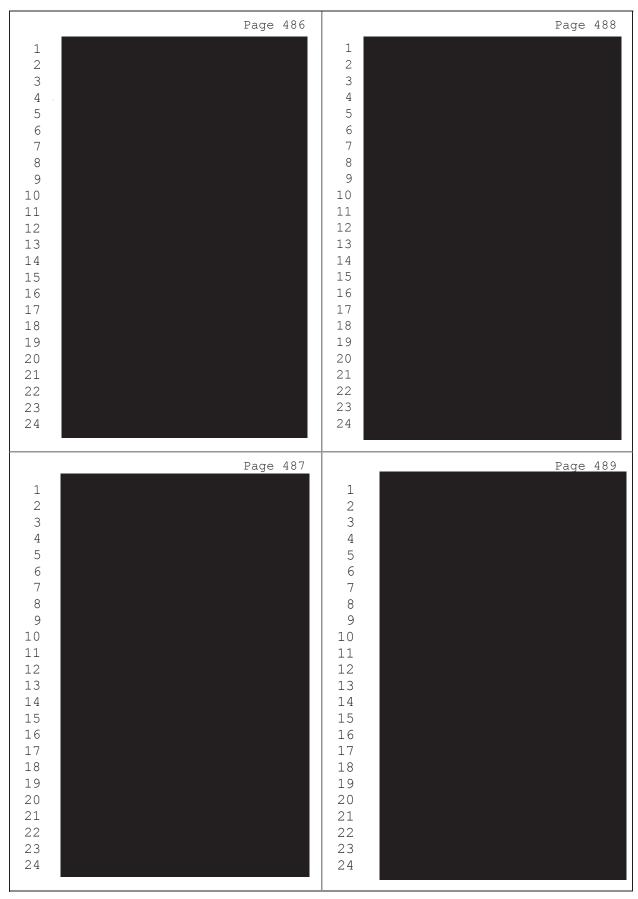
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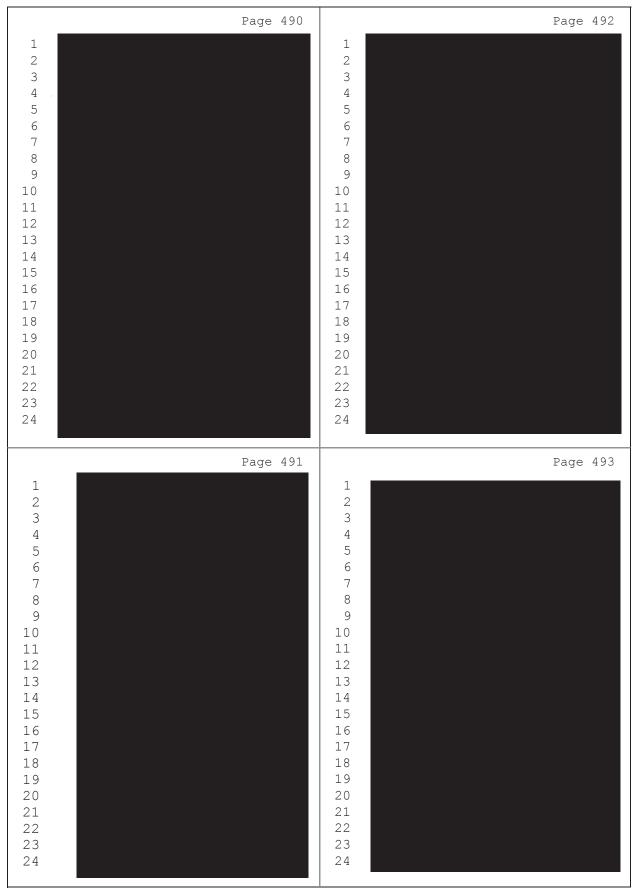
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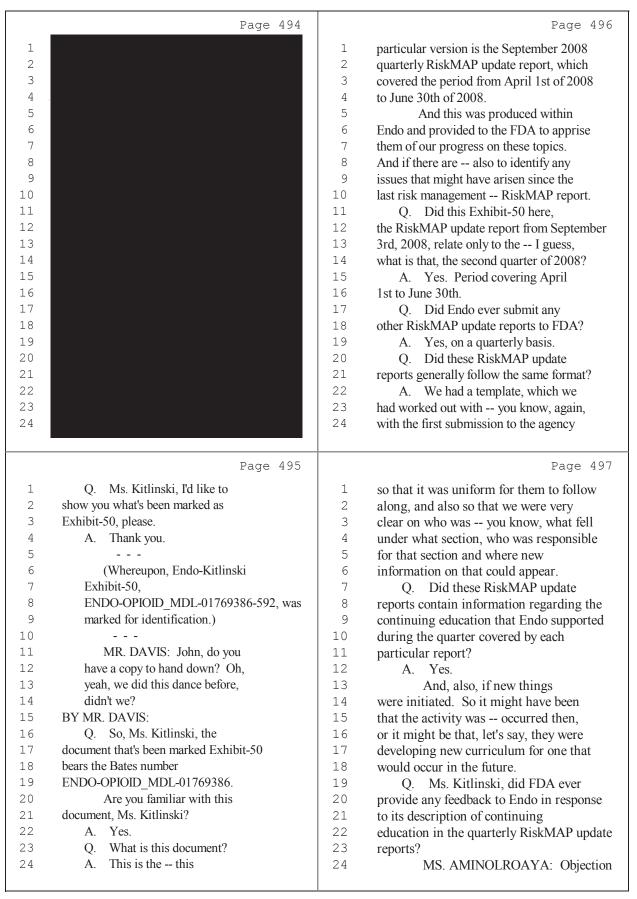
122 (Pages 482 to 485)



123 (Pages 486 to 489)



124 (Pages 490 to 493)



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Page 498
                                                                                             Page 500
                                                        1
 1
            to form. You're asking, sorry, if
                                                                  O. Did FDA ever tell Endo that
            FDA provided feedback in the
                                                        2
 2
                                                              the education it was supporting minimized
 3
            RiskMAPs that Endo submitted?
                                                        3
                                                              the risks of abuse or misuse of opioids?
                MR. DAVIS: Let me ask it
                                                        4
                                                                     MS. AMINOLROAYA: Same
 4
                                                        5
 5
                                                                  objection.
            again.
                                                        6
 6
        BY MR. DAVIS:
                                                                     THE WITNESS: No.
 7
            Q. Ms. Kitlinski, did Endo ever
                                                        7
                                                              BY MR. DAVIS:
 8
        provide any feedback -- did FDA -- I'll
                                                        8
                                                                  Q. Did FDA ever tell Endo that
                                                        9
 9
        get it right.
                                                              the education it supported minimized the
                                                      10
                                                              risk of addiction associated with
10
            A. Three times is the charm.
                                                      11
                                                              opioids?
11
            Q. Ms. Kitlinski, did FDA ever
12
        provide Endo with feedback regarding the
                                                      12
                                                                     MS. AMINOLROAYA: Object to
13
        information that Endo provided in its
                                                      13
                                                                  form.
                                                      14
14
        quarterly RiskMAP update reports
                                                                     THE WITNESS: No.
15
        regarding the continuing education -- the
                                                      15
                                                              BY MR. DAVIS:
        independent education that Endo
16
                                                      16
                                                                  Q. Did FDA ever tell Endo that
                                                      17
                                                              the education it supported minimized the
17
        supported?
                                                              risk of overdose associated with opioids?
18
            A. Not --
                                                      18
19
                                                      19
                MS. AMINOLROAYA: Objection.
                                                                  A. No.
20
               THE WITNESS: Not to my
                                                      20
                                                                     MS. AMINOLROAYA: Objection.
21
            knowledge, with the exception of
                                                      21
                                                              BY MR. DAVIS:
22
            making the comment that it was,
                                                      22
                                                                  O. Does this -- does
23
            you know, a good, comprehensive
                                                      23
                                                              Exhibit-50, the RiskMAP report from
24
            program. And, in fact, I can't
                                                      24
                                                              September 3rd, 2008, Ms. Kitlinski,
                                      Page 499
                                                                                            Page 501
 1
            recall if it was Doug
                                                        1
                                                              contain information regarding the
 2
            Throckmartin, or someone who was
                                                        2
                                                              education supported by Endo during that
 3
            associated with the development of
                                                        3
                                                              quarter?
            the REMS, had referred to our
 4
                                                        4
                                                                   A. Yes, it does.
                                                        5
                                                                   Q. Can you describe for me
 5
            educational -- our RiskMAP as one
 6
            that was very thorough.
                                                        6
                                                               generally the types of education Endo
                                                        7
 7
               And so I took that as a
                                                               supported, the independent education Endo
 8
                                                        8
                                                              supported during the second quarter of
            compliment.
 9
        BY MR. DAVIS:
                                                        9
                                                              2008, please?
10
            Q. Did FDA ever say that the
                                                      10
                                                                   A. Yes. And if you look, I'll
        education that Endo was supporting was
                                                      11
                                                              just -- rather than flipping through the
11
                                                              report, I'll just work from the table of
12
        not balanced?
                                                      12
                                                              contents here.
13
                                                      13
            A. No. Absolutely --
14
                MS. AMINOLROAYA: Objection
                                                      14
                                                                       You can see that it's broken
15
                                                      15
            to form.
                                                               into several sections under education.
                                                      16
16
        BY MR. DAVIS:
                                                              Number one, the professional education
17
            Q. Did Endo ever -- or did FDA
                                                      17
                                                              initiatives. Again, those are the
18
        ever tell Endo that the education -- the
                                                      18
                                                               independent education initiatives that
19
        independent education that it was
                                                      19
                                                              were supported through unrestricted
20
        supporting was biased in any way?
                                                      20
                                                              educational grants.
21
                                                      21
                                                                       You'll see, then, there's
                MS. AMINOLROAYA: Objection
22
                                                      22
                                                              patient and -- and under that section, we
            to form.
23
               THE WITNESS: No.
                                                      23
                                                              already discussed NIPC, so folks are
24
                                                      24
                                                               familiar with that.
        BY MR. DAVIS:
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Page 502 Page 504 1 1 We talked about the I-med -activity. This was the Promise 2 initiative, which was an Endo-developed 2 we didn't call it I-med, but it was the 3 NIDA, National Institute on Drug Abuse, 3 activity for education. activity that was being coordinated by 4 So that was the professional 4 Penn State College of Medicine and NIDA. 5 5 education. We talked about many of the 6 6 The patient and family 7 collaborative efforts with the 7 education consisted of, we've talked 8 professional societies to have 8 about the Understanding Your Pain 9 brochure. There was one on the -- that 9 educational activities at their annual 10 was not in this section, on pain rating, 10 conferences. 11 We talked about the 11 pain assessment inventory. 12 12 So when you're going to your residents/physician in training 13 13 physician, how you can, you know, capture initiative. on the pain scale what your pain rating 14 We spoke about painEDU, 14 15 which was the Inflexxion website, and 15 was, where the source of your pain was, manual for clinicians. descriptors for the pain. 16 16 17 And then we spoke about the 17 And then the Pain Action ACPE, accredited pharmacy education 18 18 website, which had materials that could 19 19 be downloaded, similar to those tear-pads monographs. 20 20 I think it's interesting you that we were discussing for the state of 21 asked me about the evolution of things. 21 Tennessee, you know, helping to educate 22 In my capacity, one of my 22 families and caregivers on safe use and 23 responsibilities at DuPont Merck was 23 safe storage principles. 24 actually -- we were an accredited ACPE 2.4 And then beyond that, the Page 503 Page 505 1 1 provider, so my activities there did other area that we supported through involve directly working with the faculty 2 educational grants was the development of 2 3 and developing pharmacy education 3 psychometrically validated tools to help modules, maintaining the accreditation assess patients who were being considered 4 4 documents for that. And being, you know, 5 for opioid therapy, that would be the 5 6 6 in industry, you were ultra sure that you SOAPP tool, or who were already on opioid 7 were not only adhering but, you know, 7 therapy to manage them and to assure that 8 exceeding those standards. 8 their risks were mitigated; so that was 9 9 So I had -- I know there was SOAPP and CON. 10 10 one area where someone was asking about a So those were the types of 11 pharmacy monograph and the fact that we 11 activities that were in our RiskMAP. 12 were, you know, being involved with that. 12 Q. In addition to listing all And that was perfectly acceptable. 13 of those educational activities in the 13 14 We talked about the opioid 14 table of contents, does this RiskMAP 15 15 handbooks; the principles of analgesic report from September of 2008 contain any use; supporting the purchase of 16 further information about those 16 17 evidence-based guidelines. 17 educational activities? 18 And then risk management 18 A. It has a summary for each of 19 information and tools for clinicians --19 those. I mean, in the purposes of time, 20 I'll just refresh my memory on what 20 I just gave you my one-word CliffsNote 21 specifically that was that we hadn't 21 version of it. 22 already talked about. 22 But each of those areas 23 23 Oh, this was -- this was would have a paragraph, two paragraphs or 24 actually not an independent educational 24 longer, describing what was relative for

	Page 506		Page 508
1	that quarter.	1	BY MR. DAVIS:
2	Q. Did you review other	2	Q. In response to any of the
3	quarterly RiskMAP update reports, other	3	quarterly RiskMAP update reports, did FDA
4 .	than this one from September 2008, Ms.	4	ever tell Endo to stop supporting any
5	Kitlinski?	5	particular educational activity?
6	MS. AMINOLROAYA: Objection	6	A. No.
7	to the form.	7	MS. AMINOLROAYA: Objection
8	THE WITNESS: I	8	to form.
9	MS. AMINOLROAYA: Can we	9	BY MR. DAVIS:
10	specify what time period the	10	Q. Ms. Kitlinski, does the
11	question relates to?	11	did the RiskMAP I know you talked to
12	MR. DAVIS: During the	12	this a second ago you can set that
13	course of the RiskMAP.	13	aside if you'd like.
14	THE WITNESS: Yes. We would	14	Does the Opana ER did the
15		15	
	do this on a quarterly basis. So		Opana ER RiskMAP cover other areas beyond
16	once a quarter I would prepare my	16	independent education?
17	sections, I would submit it to the	17	A. Yes.
18	regulatory team. They would	18	Q. Did you have responsibility
19	incorporate the other sections	19	for those areas?
20	from the other departments and	20	A. No, I did not.
21	produce the final version like	21	Q. Were there others at Endo
22	we're looking at here.	22	that had responsibility for those areas?
23	BY MR. DAVIS:	23	A. Yes. So the individuals in
24	Q. Did the other RiskMAP,	24	each department would produce their
	Daga 507	1	
	Page 507		Page 509
1	quarterly RiskMAP reports that you	1	section of the report, and it would be
1 2	_	1 2	
	quarterly RiskMAP reports that you		section of the report, and it would be
2	quarterly RiskMAP reports that you reviewed, contain a similar number of	2	section of the report, and it would be compiled by the regulatory department.
2	quarterly RiskMAP reports that you reviewed, contain a similar number of educational activities?  A. Yes. We are always	2 3	section of the report, and it would be compiled by the regulatory department.  Q. Do you know whether and,
2 3 4	quarterly RiskMAP reports that you reviewed, contain a similar number of educational activities?  A. Yes. We are always committed to a very robust risk	2 3 4	section of the report, and it would be compiled by the regulatory department.  Q. Do you know whether and, Ms. Kitlinski, you just referenced the
2 3 4 5	quarterly RiskMAP reports that you reviewed, contain a similar number of educational activities?  A. Yes. We are always committed to a very robust risk mitigation strategy. That's why we	2 3 4 5	section of the report, and it would be compiled by the regulatory department.  Q. Do you know whether and, Ms. Kitlinski, you just referenced the REMS.  A. Yes.
2 3 4 5 6 7	quarterly RiskMAP reports that you reviewed, contain a similar number of educational activities?  A. Yes. We are always committed to a very robust risk mitigation strategy. That's why we developed this in the first place.	2 3 4 5 6	section of the report, and it would be compiled by the regulatory department.  Q. Do you know whether and, Ms. Kitlinski, you just referenced the REMS.  A. Yes. Q. Did Endo did the REMS
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	quarterly RiskMAP reports that you reviewed, contain a similar number of educational activities?  A. Yes. We are always committed to a very robust risk mitigation strategy. That's why we developed this in the first place. That's why we did it, even though it wasn't required.  Q. Did FDA ever respond to any of the quarterly RiskMAP update reports let me ask a better question.  In response to any of the RiskMAP update reports, did FDA ever ask Endo to support different educational activities?  A. No. We did not  MS. AMINOLROAYA: Object to form.  THE WITNESS: Until the REMS came out, in which case that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	section of the report, and it would be compiled by the regulatory department.  Q. Do you know whether and, Ms. Kitlinski, you just referenced the REMS.  A. Yes. Q. Did Endo did the REMS were you referring to the extended-release long-acting opioid REMS?  A. Yes, that's correct. Q. And does I'll just refer to that as the REMS for now.  A. Yes. Q. Did the REMS contain an educational component?  A. Yes, it did. They call it training in the REMS language, but we worked through that with them so they understood it was education and we understood it was training, and we used the words, you know, education/training.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	quarterly RiskMAP reports that you reviewed, contain a similar number of educational activities?  A. Yes. We are always committed to a very robust risk mitigation strategy. That's why we developed this in the first place. That's why we did it, even though it wasn't required.  Q. Did FDA ever respond to any of the quarterly RiskMAP update reports let me ask a better question.  In response to any of the RiskMAP update reports different educational activities?  A. No. We did not  MS. AMINOLROAYA: Object to form.  THE WITNESS: Until the REMS came out, in which case that applied to not just Endo, but the REMS, you know, applied to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	section of the report, and it would be compiled by the regulatory department.  Q. Do you know whether and, Ms. Kitlinski, you just referenced the REMS.  A. Yes. Q. Did Endo did the REMS were you referring to the extended-release long-acting opioid REMS?  A. Yes, that's correct. Q. And does I'll just refer to that as the REMS for now.  A. Yes. Q. Did the REMS contain an educational component?  A. Yes, it did. They call it training in the REMS language, but we worked through that with them so they understood it was education and we understood it was training, and we used the words, you know, education/training.  Q. Did Endo continue to support independent education following the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	quarterly RiskMAP reports that you reviewed, contain a similar number of educational activities?  A. Yes. We are always committed to a very robust risk mitigation strategy. That's why we developed this in the first place. That's why we did it, even though it wasn't required.  Q. Did FDA ever respond to any of the quarterly RiskMAP update reports let me ask a better question.  In response to any of the RiskMAP update reports, did FDA ever ask Endo to support different educational activities?  A. No. We did not  MS. AMINOLROAYA: Object to form.  THE WITNESS: Until the REMS came out, in which case that applied to not just Endo, but the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	section of the report, and it would be compiled by the regulatory department.  Q. Do you know whether and, Ms. Kitlinski, you just referenced the REMS.  A. Yes. Q. Did Endo did the REMS were you referring to the extended-release long-acting opioid REMS?  A. Yes, that's correct. Q. And does I'll just refer to that as the REMS for now.  A. Yes. Q. Did the REMS contain an educational component?  A. Yes, it did. They call it training in the REMS language, but we worked through that with them so they understood it was education and we used the words, you know, education/training. Q. Did Endo continue to support

	Page 510		Page 512
1	MS. AMINOLROAYA: Objection	1	confusion that if you were a
2	to form.	2	practicing clinician and you
3	THE WITNESS: We did for a	3	participated in this activity that
4 .	period of time. And then there	4	was three hours long and talked
5	were concerns that by so I'll	5	about the safer use of opioids,
6	step back for a second.	6	you would have considered that you
7	The REMS, besides requiring	7	can completed, you know,
8	education, established goals of	8	appropriate education on opioids.
9	how many they called them	9	You would not be likely to then
10	completers, how many clinicians	10	sit through another three hours of
11	needed to have completed training,	11	REMS-compliant training.
12	their word, on the full blueprint	12	And so that was one of the
13	in order to count towards the REMS	13	big things we learned up front was
14	goals.	14	clinicians don't know or care what
15	So the FDA had very strict	15	REMS means; if you talk about safe
16	goals of what was required within,	16	use of opioids, they'll be
17	you know, the first year of the	17	interested in that. If you say
18	REMS being available and the	18	you should go to this because it's
19	second year, et cetera.	19	an FDA REMS-mandated activity,
20	And because of the length of	20	they probably care less.
21	the the length of the	21	So we tried to not dilute
22	blueprint, which, therefore,	22	the pool of physicians and
23	dictated the length of the CE	23	clinicians who were willing to,
24	activities, many of them were	24	
2 1	activities, many of them were	24	you know, participate in the REMS
	Page 511		Page 513
1	three hours long, two and-a-half	1	education, because that was
2	hours, three hours, even a little	2	mandatory for us because we had
3	bit longer than that. There	3	goals that we had to meet.
4	was you know, clinicians are	4	And so while we were trying
5	busy and, again, were not	5	to do the right thing by offering
6	necessarily standing in line to	6	greater diversity of education, it
7	give up three or four hours of	7	became apparent that that was
8	their time to participate in an	8	having a potential negative effect
9	educational activity, albeit CE	9	on people participating on the
10	accredited, and albeit one of key	10	REMS.
11	importance.	11	BY MR. DAVIS:
12	So what we realized after	12	Q. At that point, did Endo
13	the first year was that we were	13	continue to support independent education
14	potentially because there was a	14	through its participation in REMS?
15	lot of if there was other	15	A. Yes, we did.
16	opioid education, so, for example,	16	Q. Did FDA were you aware of
17	NIDA, I remember having a	17	whether the REMS consortium shared any
18	discussion with NIDA, who had done	18	information with FDA?
19	a Medscape activity talking about	19	A. With regards to the progress
20	the responsible use of opioid	20	on the REMS, is that what you're
21	analgesics, and it was three hours	21	referring to?
22	long, again, which was similar to	22	Q. I'm specifically talking
23	the REMS.	23	about the content of the education
24	So there was a lot of	24	supported by the REMS consortium.
	So there was a lot of		supported by the relatio consortium.

Page 514 Page 516 1 1 MS. AMINOLROAYA: Objection requirement to have a realtime website 2 2 that would list -- and it was searchable, to form. 3 THE WITNESS: So the RPC, 3 if you were a primary care physician in 4 Pennsylvania and you were looking to 4 the REMS program companies, 5 participate in a REMS education activity, 5 provided a -- again, a report, a periodic report to the FDA, the 6 you would be able to do a keyword search 6 7 first ones were shorter periods of 7 and find either live or online activities 8 time, the others were, you know, 8 that were, you know, aligned with your 9 9 24, 36 months, et cetera, advising interests. them of the progress, in terms of 10 10 So the FDA received regular the metrics, the REMS metrics, 11 updates on that as well. 11 12 12 where we stood with regard to the O. Ms. Kitlinski, did Endo 13 goals they had determined, where 13 exercise any control over the content of the independent education it supported 14 we stood with regards to the 14 15 evaluations, you know, we were 15 through the RiskMAP? talking about the fact that 16 16 MS. AMINOLROAYA: Objection education -- accredited education 17 17 to form. 18 needs to have a metric for 18 THE WITNESS: Through the --19 determining whether you've 19 through the RiskMAP? 20 accomplished -- whether the CE 20 BY MR. DAVIS: 21 provider has accomplished the 21 Q. Yes. 22 goals they set out to do. 22 A. Again, Endo did not 23 So all of that information 23 contribute -- control, exert influence or 24 was communicated periodically in a 24 control the content because, ultimately, Page 515 Page 517 1 very lengthy report to the FDA. 1 that resided with the CE provider and 2 BY MR. DAVIS: 2 with the faculty and the program 3 Q. Did the FDA ever provide 3 development team. 4 4 direction to the REMS program companies I do say, as I said before, about the types of independent education 5 in the early days, when appropriate and 5 6 those companies should be supporting 6 compliant with the guidelines, when 7 7 through their participation in REMS? asked, we did provide input on broad 8 A. No. They were part of the 8 topics, potential faculty who were -- who 9 9 discussions of what the intent was. And were therapeutic experts or a courtesy 10 it was emphasized that it was to reach a 10 medical review for looking for medical 11 broad audience of especially primary care 11 accuracy regarding our information. 12 12 Q. In those early days, would providers. 13 Endo provide specific content related to 13 They knew how, in fact, we the broad topics it had offered? 14 had sent the request for proposal, the 14 draft, to them in advance of putting it 15 15 A. No. 16 out there to the CE community to make 16 Did Endo exert any control 17 sure that they knew what we were asking 17 over the content of the independent 18 for and to make sure that it was aligned 18 education supported through REMS? 19 19 MS. AMINOLROAYA: Objection with their expectations. And they received reports 20 20 to form. 21 21 from the REMS companies, for example, THE WITNESS: No. And 22 after each grant cycle saying, these are 22 the -- again, I'll preface this, 23 the grants that have been -- have been 23 since this whole REMS was a little 24 approved. Part of the REMS was the 24 bit of a different -- sort of a

different animal, part of the REMS blueprint, which FDA did require each company to submit, was Section 6 of the REMS blueprint was product-specific information on each of the ERLA opioid REMS products.  So, for example, for Endo, Opana ER, we were required to submit a one-page summary of contraindications, warning, 12 dosage, any particular risk issues that were in the labeling so that if a clinician was going to prescribe any one of the ERLA opioids, they could look at 16 provide our regulatory and our 23 R&D teams provided that to the FDA, again, made sure  Page 519  that it was appropriately vetted the labeling, and also that it was vetted through their own internal organization and consistent with the labeling, and also that it was vetted through their own internal organization and consistent with the labeling, and also that it was vetted through their own internal organization and consistent with the labeling, and also that it was vetted through the DHHS, HHS, NIDA, SAMSA folks who were also reviewing everything.  So, again, that was the work product of the FDA, which was what the blueprint was, but we did have the labeling rather that responsibility to prosent that one-page synopsis on our particular products.  different animal, part of the RELA opioid REMS information. Can we start with Exhibit-35, please? And this is, again, just for the record, Bates labeled ENDO-OPIOID_MDL-06234029.  Do you recall discussion of this document, Ms. Kitlinski?  A. Yes.  Q. And what is this document?  A. This was a an update from the American Pain Foundation to Endo about its when John Giglio took over the responsibilities there, the overview of the American Pain Foundation, what some of their recent accomplishments were, where they were heading in the future.  Q. Do you recall questions about Endo's support for the recent APF accomplishments described in this document?  A. I do, yes.  Q. And do you see that sentence  Page 519  That it was appropriately vetted through their own internal and consistent with th	ļ			D 500
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the sort of relevant issues were for that particular drug, as opposed to for the class.  And so that we were asked to provide our regulatory and our R&D teams provided that to the through their own internal organization and consistent with the labeling, and also that it was vetted through the DHHS, HHS, NIDA, SAMSA folks who were also reviewing everything. So, again, that was the work product of the FDA, which was what the blueprint was, but we did have that that responsibility to our particular products.  BY MR. DAVIS: Opposed to for the class.  19 Q. Do you recall questions about Endo's support for the recent APF accomplishments described in this document? A. I do, yes. Q. And do you see that sentence  Page 519  Page 521  on the second page of this document? A. With support Page 2 here, With support from Endo? Q. Yes. A. Yes. Q. Was Endo the only funder of APF's recent accomplishments? A. No. As I pointed out when we were going through the brochure itself as well, there were many other funders, both industry and nonindustry supporters.  Q. Do you recall plaintiffs' coursel asking you about the patient education materials described on Page 3 of the document?	16	opioids, they could look at	16	some of their recent accomplishments
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13 our particular products.  14 BY MR. DAVIS:  15 Q. Separate and apart from that  13 counsel asking you about the patient education materials described on Page 3  15 of the document?				
14 BY MR. DAVIS: 15 Q. Separate and apart from that 14 education materials described on Page 3 15 of the document?				
15 Q. Separate and apart from that 15 of the document?				
I ± ∨ OHO-DAZO SYNODSIS, UIU ENUO OAGII ANY I ± ∪ A IES	16	one-page synopsis, did Endo exert any	16	A. Yes.
control over the independent education 17 Q. Were those patient education				
18 supported through REMS? 18 materials the only recent APF				
19 A. No. 19 accomplishments described in this letter?				•
20 MS. AMINOLROAYA: Objection 20 A. No. As you can see, there				
j	<b>2</b> 0			
1				
	21	DI MIX. DAVIO.		
, with the title of pull hammen and the	21 22			
	21 22 23	Q. Ms. Kitlinski, I'd like to ask you about a few of the documents that	23	work in the field of pain management and advocacy.

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Page 522
                                                                                                 Page 524
 1
            Q. You just said "pain
                                                           1
                                                                  exit strategy so that the patient
 2
        management" there, Ms. Kitlinski.
                                                           2
                                                                  understood this was a trial.
 3
               Does that mean opioids?
                                                           3
                                                                      O. Let's look at one of the
            A. Opioids are one element of
 4
                                                           4
                                                                  patient education materials referred to
 5
        pain management. But what American Pain
                                                           5
                                                                  in this APF document. It's Exhibit-36.
        Foundation, and all of the other national
                                                           6
 6
                                                                  And that bears the Bates number
 7
        pain organizations, are committed to,
                                                           7
                                                                  CHI000435580.
 8
        unless it was a specific one like the
                                                          8
                                                                          Do you recall discussing
        Varicella Zoster Foundation, which was
 9
                                                          9
                                                                  this document with plaintiffs' counsel,
10
        only associated with that particular area
                                                         10
                                                                  Ms. Kitlinski?
11
        of pain, but for the majority, the
                                                         11
                                                                      A. Yes.
        American Chronic Pain Association, the
                                                                      O. And what is this document?
12
                                                         12
        National Pain Foundation, the ACPA, all
13
                                                         13
                                                                      A. Again, this is a,
14
        of the professional organizations, their
                                                         14
                                                                  quote/unquote, pain action guide, a
15
        goal was much broader. It was for
                                                                  brochure that was developed by the
                                                         15
        correct and appropriate assessment of
                                                                  American Pain Foundation talking about
16
                                                         16
17
        patients, assuring that patients were
                                                         17
                                                                  the -- again, pain in general, as we've
        able to describe their needs to their
                                                         18
                                                                  been discussing all day, that there are
18
19
        clinicians, assuring that clinicians had
                                                         19
                                                                  two concomitant public health situations.
20
        access to a broad spectrum of analgesic
                                                         20
                                                                  One is chronic pain and the other is the
        modalities, whether they be
21
                                                         21
                                                                  public health situation associated with
22
        pharmacologic, nonpharmacologic, you
                                                         22
                                                                  abuse and misuse of opioid analgesics.
23
        know, combination, multimodal therapies.
                                                         23
                                                                          This was to give information
24
        all of those
                                                         2.4
                                                                  to patients that they could discuss with
                                        Page 523
                                                                                                 Page 525
 1
                So that's what pain
                                                          1
                                                                 their families and their caregivers.
  2
        management is when I use that term. And
                                                          2
                                                                 Sort of simple lay language like, what
  3
        certainly opioids is one element of that.
                                                           3
                                                                 can I do? Talk to your doctor and nurse
             O. But just one element, right?
                                                           4
                                                                 about pain. It's a common medical
  4
  5
             A. Yes. And certainly not the
                                                          5
                                                                 problem that requires attention, so you
        first element. All of the -- I know that
  6
                                                           6
                                                                 shouldn't be ashamed to talk about it.
                                                          7
  7
        there were some sentences or bullet
                                                                 Tell your doctor or nurse where it hurts
  8
                                                          8
                                                                 so they can help localize it. Describe
        points that pointed out today about
                                                          9
  9
        opioids and, perhaps, someone might have
                                                                 how much your pain hurts. So it was
10
        mistakenly believed that that was the
                                                         10
                                                                 practical, lay language that could be
        first alternative that was recommended in
11
                                                         11
                                                                 utilized.
12
        all of these educational materials,
                                                         12
                                                                          And resources. Keep a pain
        whether they were independent or
                                                         13
                                                                 diary. You know, use a pain rating
13
14
        otherwise.
                                                         14
                                                                 scale. That type of thing.
15
                                                         15
                                                                      Q. Do you recall plaintiffs
                 And, indeed, without
        exception, they all indicated that opioid
                                                         16
                                                                 asking you questions about this document?
16
17
        should be used when other modalities have
                                                         17
                                                                      A. I recall us -- I recall us
18
        failed to provide sufficient pain relief
                                                         18
                                                                 talking about the document. And I know
19
        or when there are untoward issues which
                                                         19
                                                                 that we asked at least one question on
        necessitated adding an opioid or
                                                         20
20
21
        considering adding an opioid.
                                                         21
                                                                      Q. How many pages is this
22
                And, again, in all
                                                         22
                                                                 document?
        instances, the education emphasized the
23
                                                         23
                                                                      A. It looks like 14.
24
        need, right from the get-go, of having an
                                                         24
                                                                      Q. How many pages did
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	Page 526		Page 528
1	plaintiffs ask you about?	1	asking you about any slide other than the
2	A. I believe it was one point	2	top slide on the page that bears the
3	on one page.	3	Bates number ending 8066?
4 .	Q. Okay. They did not ask you	4	A. No, I do not. It was the
5	about the whole document, did they?	5	pseudoaddiction was the only point that
6	A. No.	6	they raised out of this.
7	Q. They did not ask you about	7	Q. Did they did plaintiffs
8	anything other than this one point on	8	ask you about, if you flip to the
9	Page 6, correct?	9	beginning, about the agenda for the
10	A. Yes, that's correct.	10	fundamentals of pain management program?
11	Q. Okay. They didn't ask you	11	A. No.
12	about, for example, on Page 10,	12	Q. Do all of the sessions
13	suggestions to ask your doctor or nurse	13	described over the several days of this
14	about nondrug, nonsurgical treatments,	14	program relate to opioids?
15	did they?	15	A. Not by a long shot, no.
16	A. No.	16	There is one session on pain
17	Q. Did they ask you questions	17	pharmacology well, first of all, to
18	about the suggestion that a patient ask	18	take a step back. It's not even that
19	their doctor or nurse about ways to relax	19	there are the whole sessions relate to
20	and cope with pain?	20	pharmacologic therapy. It talks about
21	A. No.	21	assessment and physical exam and taking a
22	Q. Okay. You can set that one	22	history.
23	aside.	23	And then there is one
24	Let's look at Exhibit-40,	24	session on pain pharmacology presented by
	Let's look at L'Amort 10,		contain on pain prantationegy processes of
	Page 527		Page 529
1	Page 527 please. And this exhibit bears the Bates	1	Dr. Barry Kohl, after the pain
2	_	1 2	
	please. And this exhibit bears the Bates	1	Dr. Barry Kohl, after the pain
2 3 4	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029.	2	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is
2 3 4 5	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029. Ms. Kitlinski, do you recall	2 3	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.
2 3 4	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029. Ms. Kitlinski, do you recall this document?	2 3 4	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff. There is also, on the second
2 3 4 5	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029. Ms. Kitlinski, do you recall this document? A. Yes. This was part of the	2 3 4 5	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of
2 3 4 5 6	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029. Ms. Kitlinski, do you recall this document? A. Yes. This was part of the syllabus from the American Pain Society	2 3 4 5 6	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of aberrant behaviors associated with
2 3 4 5 6 7 8 9	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029.  Ms. Kitlinski, do you recall this document?  A. Yes. This was part of the syllabus from the American Pain Society residents course.  Q. Let's flip to the primer and the syllabus.	2 3 4 5 6 7 8 9	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of aberrant behaviors associated with analgesic use.  So those are the only unless I'm missing, my guess here, the
2 3 4 5 6 7 8 9	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029.  Ms. Kitlinski, do you recall this document?  A. Yes. This was part of the syllabus from the American Pain Society residents course.  Q. Let's flip to the primer and the syllabus.  Just ballpark, how many	2 3 4 5 6 7 8 9	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of aberrant behaviors associated with analgesic use.  So those are the only unless I'm missing, my guess here, the only opioid-related courses. And
2 3 4 5 6 7 8 9 10	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029.  Ms. Kitlinski, do you recall this document?  A. Yes. This was part of the syllabus from the American Pain Society residents course.  Q. Let's flip to the primer and the syllabus.  Just ballpark, how many pages is this syllabus?	2 3 4 5 6 7 8 9 10	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of aberrant behaviors associated with analgesic use.  So those are the only unless I'm missing, my guess here, the only opioid-related courses. And methadone, I'm sorry, the devil is in the
2 3 4 5 6 7 8 9 10 11	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029.  Ms. Kitlinski, do you recall this document?  A. Yes. This was part of the syllabus from the American Pain Society residents course.  Q. Let's flip to the primer and the syllabus.  Just ballpark, how many	2 3 4 5 6 7 8 9 10 11 12	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of aberrant behaviors associated with analgesic use.  So those are the only unless I'm missing, my guess here, the only opioid-related courses. And methadone, I'm sorry, the devil is in the details, sort of discussing the dosing
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2 3 4 5 6 7 8 9 10 11 12 13 14	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029.  Ms. Kitlinski, do you recall this document?  A. Yes. This was part of the syllabus from the American Pain Society residents course.  Q. Let's flip to the primer and the syllabus.  Just ballpark, how many pages is this syllabus?  A. It looked about 50 pages, printouts.  Q. And many of the pages	2 3 4 5 6 7 8 9 10 11 12 13 14	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of aberrant behaviors associated with analgesic use.  So those are the only unless I'm missing, my guess here, the only opioid-related courses. And methadone, I'm sorry, the devil is in the details, sort of discussing the dosing challenges and the very variable and extended half-life of that drug.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	please. And this exhibit bears the Bates number ENDO-OPIOID_MDL-05968029.  Ms. Kitlinski, do you recall this document?  A. Yes. This was part of the syllabus from the American Pain Society residents course.  Q. Let's flip to the primer and the syllabus.  Just ballpark, how many pages is this syllabus?  A. It looked about 50 pages, printouts.  Q. And many of the pages contain more than one slide?  A. There are generally three slides, three up on each page; so 150 slides, approximately.  Q. Do you recall how many of these slides plaintiffs asked you about?  A. I do not, but I believe it	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Dr. Barry Kohl, after the pain pharmacology of nonopioid analgesics is presented by Dr. Argoff.  There is also, on the second day, the assessment and management of aberrant behaviors associated with analgesic use.  So those are the only unless I'm missing, my guess here, the only opioid-related courses. And methadone, I'm sorry, the devil is in the details, sort of discussing the dosing challenges and the very variable and extended half-life of that drug.  Q. Did plaintiffs ask you about any of the nonopioid-related sessions for the fundamentals of pain management section?  A. No.  Q. Did they ask you about any of the other many slides contained in this document, other than the one that we

```
Page 530
                                                                                              Page 532
                                                         1
 1
           O. You can set that one aside.
                                                               Tramadol is an atypical agent, but could
                                                         2
 2
        Ms. Kitlinski.
                                                               be characterized as an opioid as well.
 3
               I'd like you to look at
                                                         3
                                                               So there might be four pages there.
        Exhibit-42, please, if you would. This
                                                         4
                                                                    Q. And how many pages is this
 4
        document bears a number of Bates numbers,
                                                         5
 5
                                                               guideline?
        but I'll go with the one at the bottom,
                                                         6
 6
                                                                    A. It looks to be about 131,
                                                         7
 7
        which is, I think, the one cited in the
                                                               plus the appendices and index.
 8
       record thus far, which is PYK181215547.
                                                         8
                                                                    Q. And was this an APS
                                                         9
               Do you recall this document,
                                                               guideline?
 9
10
        Ms. Kitlinski?
                                                       10
                                                                    A. Yes.
11
                                                       11
                                                                    Q. When I say "APS," do you
           A. Yes.
                                                       12
                                                               understand me to mean the American Pain
12
           O. What is this document?
13
           A. This is the guideline for
                                                       13
                                                               Society?
        osteoarthritis, rheumatoid arthritis and
14
                                                       14
                                                                    A. The American Pain Society,
15
       juvenile chronic arthritis that was
                                                       15
                                                               ves.
       developed by the American Pain Society in
16
                                                       16
                                                                    Q. And do you have an
                                                       17
                                                               understanding of the American Pain
17
        2002.
                                                               Society's objectives?
18
            Q. And did plaintiffs ask you
                                                       18
        about any of the content of this
19
                                                       19
                                                                        MS. AMINOLROAYA: Objection
20
                                                       20
        document?
                                                                    to form.
21
           A. I don't believe so. We read
                                                       21
                                                                       THE WITNESS: Well, I
22
        it up -- and we were talking about it --
                                                       22
                                                                    believe they -- they lay it out
23
        about guidelines, but I don't believe
                                                       23
                                                                    here in the preface, which is
24
        that we actually delved into any of the
                                                       24
                                                                    intending -- they convened an
                                       Page 531
                                                                                              Page 533
                                                                    arthritis pain management panel
 1
        content here.
                                                         1
 2
             O. And does -- do these
                                                         2
                                                                    over the course of two years, with
  3
        guidelines address topics other than
                                                         3
                                                                    all of the top therapeutic experts
                                                                    in rheumatology, and they worked
 4
        opioids?
                                                         4
 5
                                                         5
                                                                    with -- and orthopedic surgeons as
             A. Yes, very much so. Again,
  6
        pain assessment and the overview of the
                                                         6
                                                                    well, and developed this
 7
        pathophysiology associated with these
                                                         7
                                                                    interdisciplinary panel of experts
 8
                                                         8
                                                                    who were -- then provided the
        various disease -- arthritic types of
 9
                                                         9
                                                                    recommendations for this
        diseases.
10
                                                       10
                Certainly, the, you know,
                                                                    guideline.
        first line therapy for OA is -- are not
11
                                                       11
                                                                        So that it incorporated all
12
        opioids; Tylenol, NSAIDs, et cetera. So
                                                       12
                                                                    of the -- not just pain
                                                                    specialists, but all the
13
        this goes through the -- goes through the
                                                       13
14
        analgesics component here, starting on
                                                       14
                                                                    specialists who manage arthritic
                                                       15
15
        Page 54, talking about analgesics,
                                                                    pain.
16
        acetaminophen, nonsteroidals, topical
                                                       16
                                                                BY MR. DAVIS:
17
        agents, hyaluronic acid, et cetera,
                                                       17
                                                                    Q. You can set that aside, Ms.
                                                       18
18
        DMARDs.
                                                                Kitlinski.
                                                       19
                                                                        Will you look at Exhibit-43,
19
                And then there is, it looks
                                                                please? And this bears the Bates number
20
        like, three pages on opioids, the first
                                                       20
21
        of which is addiction, physical
                                                        21
                                                                END00051370.
        dependence and tolerance. One page on
                                                       22
22
                                                                        Do you recall this document,
2.3
        the effectiveness and use of opioids.
                                                       23
                                                                Ms. Kitlinski?
        And then one page on opioid dosing.
24
                                                        24
                                                                    A. Yes, I do.
```

	Page 534		Page 536
1	Q. What is this document?	1	Q. And what are those public
2	A. This is the handbook	2	important public health trends described
3	entitled, Responsible Opioid Prescribing,	3	by this book?
4 .	a Physician's Guide, that was authored by	4	A. Well, this is a really, I
5	Scott Fishman, Dr. Scott Fishman, and	5	think, appropriate way of depicting here
6	distributed made available through the	6	the twin serpents in the caduceus,
7	Federation of State Medical Boards.	7	right? So you've got the public health
8	Q. How many pages is this	8	trend of the shifting patterns of drug
9	document, Ms. Kitlinski?	9	abuse from illicit to prescription drugs,
10	A. It looks to be about 125	10	a notable rise in diversion and
11	pages.	11	nonmedical use of opioid pain
12	Q. Do you recall plaintiffs	12	medications, and then on the flip side of
13	asking you questions about this document?	13	it, the attention that pain in general,
14	A. We did look at one point in	14	chronic pain, is often undertreated or
15	here.	15	undiagnosed.
16	Q. Do you recall how many pages	16	And so it's, as the author
17	they asked you questions about?	17	puts it, the perfect storm, if you will,
18	A. I know it was at least one.	18	of clinicians needing to manage those
19	I'm sorry, I don't.	19	dual public health crises in a reasonable
20	Q. Okay. Let's look at Page	20	way.
21	28, please, of the actual book copy, not	21	Q. Does this language recognize
22	the number up top, sorry.	22	the risk associated with opioid
23	A. That's all right.	23	analgesics?
24	Q. Do you recall do you see	24	MS. AMINOLROAYA: Objection
	Page 535		Page 537
1		1	Page 537 to form.
1 2	the	1 2	to form.
	the A. Oh, yes.	2	-
2	the A. Oh, yes. Q do you recall plaintiffs		to form. THE WITNESS: Absolutely. BY MR. DAVIS:
2 3 4	the A. Oh, yes. Q do you recall plaintiffs asking you about any other section of	2 3 4	to form. THE WITNESS: Absolutely. BY MR. DAVIS: Q. And what does it say about
2 3 4 5 6	the A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on	2 3	to form. THE WITNESS: Absolutely. BY MR. DAVIS:
2 3 4 5	the A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28?	2 3 4 5	to form.  THE WITNESS: Absolutely. BY MR. DAVIS: Q. And what does it say about the risk of opioid analgesics?
2 3 4 5 6 7 8	the A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28?	2 3 4 5 6	to form.  THE WITNESS: Absolutely.  BY MR. DAVIS:  Q. And what does it say about the risk of opioid analgesics?  A. Again, it goes into the fact
2 3 4 5 6 7	the A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28? A. No. It was about patient	2 3 4 5 6 7	to form.  THE WITNESS: Absolutely.  BY MR. DAVIS:  Q. And what does it say about the risk of opioid analgesics?  A. Again, it goes into the fact that, you know, clinicians need to be
2 3 4 5 6 7 8	the A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28? A. No. It was about patient about clinicians being sued for not	2 3 4 5 6 7 8	to form. THE WITNESS: Absolutely. BY MR. DAVIS: Q. And what does it say about the risk of opioid analgesics? A. Again, it goes into the fact that, you know, clinicians need to be sensitive to and knowledgeable about
2 3 4 5 6 7 8 9 10	the A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28? A. No. It was about patient about clinicians being sued for not treating pain aggressively.	2 3 4 5 6 7 8 9	to form.  THE WITNESS: Absolutely.  BY MR. DAVIS:  Q. And what does it say about the risk of opioid analgesics?  A. Again, it goes into the fact that, you know, clinicians need to be sensitive to and knowledgeable about pharmacovigilance and risk management.
2 3 4 5 6 7 8 9	A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28? A. No. It was about patient about clinicians being sued for not treating pain aggressively. Q. Will you look at Page 5 of	2 3 4 5 6 7 8 9 10 11 12	to form.  THE WITNESS: Absolutely.  BY MR. DAVIS:  Q. And what does it say about the risk of opioid analgesics?  A. Again, it goes into the fact that, you know, clinicians need to be sensitive to and knowledgeable about pharmacovigilance and risk management.  It says the combination of
2 3 4 5 6 7 8 9 10 11 12 13	A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28? A. No. It was about patient about clinicians being sued for not treating pain aggressively. Q. Will you look at Page 5 of the book, please, Ms. Kitlinski?	2 3 4 5 6 7 8 9 10	to form.  THE WITNESS: Absolutely.  BY MR. DAVIS:  Q. And what does it say about the risk of opioid analgesics?  A. Again, it goes into the fact that, you know, clinicians need to be sensitive to and knowledgeable about pharmacovigilance and risk management.  It says the combination of the potential of therapeutic benefit but
2 3 4 5 6 7 8 9 10 11 12 13 14	A. Oh, yes. Q do you recall plaintiffs asking you about any other section of this book besides that one paragraph on Page 28? A. No. It was about patient about clinicians being sued for not treating pain aggressively. Q. Will you look at Page 5 of the book, please, Ms. Kitlinski? A. Page 1 of the actual book,	2 3 4 5 6 7 8 9 10 11 12 13 14	to form.  THE WITNESS: Absolutely.  BY MR. DAVIS:  Q. And what does it say about the risk of opioid analgesics?  A. Again, it goes into the fact that, you know, clinicians need to be sensitive to and knowledgeable about pharmacovigilance and risk management.  It says the combination of the potential of therapeutic benefit but the high risk associated with opioid analgesics leaves them no alternative but to become more sophisticated risk
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1 questions about that language?  2 A. No. 2 Q. Ms. Kitlinski, we saw a few 3 Q. Ms. Kitlinski, we're close. 4 We're close. I know you've been sitting 5 here for a long time. 6 A. And I may I just make one 7 additional comment?  Page 5 A. Yes.  1 A. Yes. 2 Q. Ms. Kitlinski, we saw a few documents earlier today that contains the phrase it might have just been documents, contained the phrase "RO Do you recall those?  A. Yes.	ed two DI."
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5 here for a long time. 5 documents, contained the phrase "RO 6 A. And I may I just make one 6 Do you recall those?	OI."
6 A. And I may I just make one 6 Do you recall those?	
, j	
additional comment? 7 A. Yes.	
8 Q. Please. Please. 8 Q. Do you have an understand	ng
9 A. One of the I think the 9 as to what ROI is generally?	
greatest impact of this particular tool 10 A. Well, I understand what RC	
was in the foreward, which was authored 11 generally is in the noneducation field	
by James Thompson, who was the president 12 It's the ability to determine what the	
of the Federation of State Medical 13 return on investment is for a given	
Boards, and his comment here that says, 14 initiative.	
you know, Patients in pain who rely on 15 Q. Did Endo ever conduct any	
opioids for analgesia deserve access to 16 return on investment with respect to	any
safe and effective medication; to deprive 17 of its opioid any of the	-
them of this pain relief certainly does 18 opioid-related independent education	it
them harm. Yet, these same 19 supported?	
20 life-restoring medications carry the 20 A. No. It would be	
21 potential to do grave harm to patients 21 inappropriate to do so.	
who may be at risk for addiction and 22 And, you know, return on	
23 abuse. Significant quantities of 23 ROI is not the same as discussing a	
prescription opioids are diverted into 24 return on education, in terms of, you	
prostription optones are arrested into	
Page 539 Page	541
the illegal black market that puts 1 know, were you able to have clinicians	be
2 millions of nonmedical, quote, 2 attracted to the program and participate	;
3 recreational users at risk of addiction 3 because it's good, quality education,	
4 and death, many of them young adults and 4 it's CE accredited, it's, you know,	
5 teenagers. While very few 5 addressing educational gaps and needs	
6 clinicians/physicians are complicit in 6 that they have.	
7 this criminal diversion and there are no 7 Q. Do you recall, Ms.	
8 proven methods from preventing patients 8 Kitlinski, discussing with plaintiffs	
9 from deceptively acquiring prescriptions, 9 their characterization of the amount of	
but the fact that some patients will 10 money that Endo had paid to these	
deceive a physician in order to obtain 11 third-party organizations?	
prescription opioids for nonmedical use 12 A. Yes.	
requires us to be vigilant when 13 Q. Do you recall plaintiffs	
prescribing these potent and potentially 14 asking you whether Endo had paid mil	ions
abusable medications. 15 of dollars to certain organizations?	
16 So, again, very strong, 16 A. Yes.	
17 emphatic statement of the recognized risk 17 Q. Did did those	
and the need to really accelerate 18 organizations retain that money?	
19 awareness of that. 19 A. No. And as I tried to point	
20 Q. Do you agree with that? 20 out on a few occasions, the educational	
21 A. Absolutely. 21 grant that is provided by Endo to any	
22 Q. Was it your understanding, 22 professional society, CE provider, or	
23 during your time at Endo, that the 23 other third-party organization, is to	
23 during your time at Endo, that the 23 other unitd-party organization, is to 24 company agreed with that language? 24 cover the entire execution of that	
2.1 company agreed with that language: 2.7 cover the chille execution of that	

	Page 542		Page 544
1	educational activity.	1	template either, but I'm just saying
2	So that would include things	2	the
3	like any associated pass-through	3	Q. Does Exhibit-44 contain
4 .	expenses, which is the majority of an	4	handwriting?
5	educational grant would be, for example,	5	A. Yes. Printing.
6	for if it was at a conference, for the	6	Q. Is any of this handwriting
7	audio/visual materials and the setup and	7	on Exhibit-44 yours?
8	the equipment and the personnel; for	8	A. No.
9	the if there was a food function	9	Q. Is any of this handwriting a
10	associated, you know, with the activity,	10	direct quote of your testimony here
11	the pass-through expenses for that.	11	today?
12	The faculty honoraria, the	12	A. No.
13	faculty travel expenses, the faculty	13	Q. How about Exhibit-21, do you
14	you know, if there were well, not	14	recall Exhibit-21?
15	if the development costs for taking	15	A. Could you scoot that over a
16	the material that the faculty provides	16	little closer? Thanks.
17	and putting it into an appropriate	17	Yes, I recall that.
18	format, a formatted presentation, for	18	Q. Had you ever seen Exhibit-21
19	example. Developing the enduring	19	before today?
20	materials, printing or posting to the	20	A. No.
21	website.	21	Q. Does Exhibit-21 contain
22	So all of those pass-through	22	handwriting today on it? I'm sorry.
23	expenses are netted are not part of	23	A. Yes.
24	the actual grant that is retained by the	24	Q. Is that your handwriting?
	viio devidur graniv viiau is recanned of viio		Q. Is that your mana withing.
	Page 543		Page 545
1	_	1	
1 2	recipient. They would be retaining the	1 2	A. No.
2	recipient. They would be retaining the portion that of a whatever their	2	A. No. Q. Whose handwriting appears on
2 3	recipient. They would be retaining the portion that of a whatever their services were involved with time or the	2 3	A. No. Q. Whose handwriting appears on Exhibit-21?
2 3 4	recipient. They would be retaining the portion that of a whatever their services were involved with time or the fee for the activity. But	2 3 4	A. No. Q. Whose handwriting appears on Exhibit-21? A. It's plaintiffs' counsel.
2 3 4 5	recipient. They would be retaining the portion that of a whatever their services were involved with time or the fee for the activity. But MS. AMINOLROAYA:	2 3 4 5	A. No. Q. Whose handwriting appears on Exhibit-21? A. It's plaintiffs' counsel. Q. And how about Exhibit-44,
2 3 4 5 6	recipient. They would be retaining the portion that of a whatever their services were involved with time or the fee for the activity. But MS. AMINOLROAYA: Objection sorry.	2 3 4 5 6	A. No. Q. Whose handwriting appears on Exhibit-21? A. It's plaintiffs' counsel. Q. And how about Exhibit-44, whose handwriting is on Exhibit-44?
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	Page 546		Page 548
1	improper demonstratives.	1	So this was CD&E's plan, in
2	MS. AMINOLROAYA: It's	2	2000, to sow the field, plant seeds and
3	several hours later.	3	then water, and then have growth as a
4 .	MR. DAVIS: One second.	4	result of that, right?
5	Thank you, Ms. Kitlinski.	5	MR. DAVIS: Objection to
6	THE WITNESS: Thank you.	6	form.
7	VIDEO TECHNICIAN: Going off	7	THE WITNESS: The
8	the record. The time is 8:33 p.m.	1	characterization of the images is
9	the record. The time is 8.33 p.m.	8 9	- C
10	(Wherever a brief record	10	not consistent. So, for example,
11	(Whereupon, a brief recess	11	one of the responsibilities of the
12	was taken.)		clinical liaison team is to go out
	VIDEO TECHNICIANI W.I	12	into the field, so this is the
13	VIDEO TECHNICIAN: We're	13	field, you know, that's the
14	back on the record at 8:57 p.m.	14	context there, and to identify,
15	EXAMPLE TYON	15	you know, what the processes are
16	EXAMINATION	16	that are in place to identify any
17		17	issues, which is, you know, sort
18	BY MS. AMINOLROAYA:	18	of the picking up the stones
19	Q. Ms. Kitlinski, do you recall	19	there, if you will, in the second
20	a discussion you had with your counsel	20	part of the graphic, to be able to
21	regarding why Endo supported independent	21	identify, shall we say, issues or
22	education?	22	concerns, like, for example, in
23	A. Yes.	23	the opioid field about the things
24	Q. Can you please look at	24	we've been discussing all day
	Page 547		Page 549
1	Exhibit-3?	1	about public health issues,
2	And this is CD&E's 2000	2	patient safety issues.
3	plan. Page 3, it's called The Critical	3	And then to in terms of
4	Connection or is entitled, The	4	the watering, if you will, to be
5	Critical Connection for Success in 2000	5	able to identify what resources
6		6	are needed to address those issues
7	and Beyond.	7	
	Do you see that on Page 3?	1	once the stones have been picked
8	A. Yes.	8	out of the field. And to provide
9	Q. And let's look at Page 4. I	9	care, show that the company is a
10	overlooked this imagery before.	10	caring company in that therapeutic
11	And what's depicted here is	11	area.
12	someone is planting seeds, correct?	12	And at the end of the day,
13	MR. DAVIS: Objection to	13	you should have a successful, new
14	form.	14	therapeutic area that you're
15	THE WITNESS: Yes, it is	15	involved with.
16	a it's a depiction of someone	16	BY MS. AMINOLROAYA:
17	sowing hoeing a row and	17	Q. Do you see stones, Ms.
18	planting seeds and watering it.	18	Kitlinski? I don't see any stones, and
19	BY MS. AMINOLROAYA:	19	we don't have to spend time on this.
20	Q. All right. And watering,	20	A. The second the second
		21	image. But that's fine.
21	and then what do we have in the last		mage. But that 5 mile.
		22	
21	and then what do we have in the last imagery here, the last image?  A. Plants.		Q. It looks like someone is
21 22	imagery here, the last image? A. Plants.	22	
21 22 23	imagery here, the last image? A. Plants.	22 23	Q. It looks like someone is dropping something on the ground.

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Page 550
                                                                                           Page 552
                                                       1
 1
        not what we see on Page 5, right? What
                                                             opposed to some other companies.
                                                       2
 2
        we see on Page 5 is, on the left-hand
                                                                     So it's not surprising that
 3
        side, we see relationships, peer
                                                       3
                                                             we would want to continue that, in having
 4
        influence and information.
                                                       4
                                                             a competitive advantage in the pain
                                                       5
 5
                So relationships, you
                                                             management area.
 6
                                                       6
        described some relationships that you
                                                                     MS. AMINOLROAYA: Move to
 7
        developed today with therapeutic experts
                                                       7
                                                                  strike after the word "yes."
 8
        or key opinion leaders.
                                                       8
                                                             BY MS. AMINOLROAYA:
                                                       9
 9
                Peer influence, is that how
                                                                  Q. And on Page 8, we see
        peer influence occurs? When experts in
                                                     10
                                                             intense -- key issues for Endo in 2000
10
                                                     11
                                                             was intense competition for key advocates
11
        the field speak to other doctors at
        continuing medical education programs?
                                                     12
                                                             and influentials, right?
12
13
                MR. DAVIS: Objection to
                                                     13
                                                                     So these were the
                                                     14
14
            form.
                                                             individuals who delivered your pain
                                                     15
15
                THE WITNESS: It's when
                                                             education, correct?
                                                     16
                                                                     MR. DAVIS: Objection to
16
            peer-to-peer exchange, scientific
                                                     17
17
            exchange, goes on, and what one
                                                                  form.
                                                     18
18
            therapeutic expert is aware of is
                                                             BY MS. AMINOLROAYA:
            conveved to his colleagues.
                                                     19
19
                                                                  Q. The second bullet there
                                                     20
20
        BY MS. AMINOLROAYA:
                                                             states, If we don't utilize, Purdue,
21
                                                     21
                                                             Parke-Davis, Abbott, Janssen will.
            Q. And information, right?
22
        Information about opioids?
                                                     22
                                                                     Did I read that correctly?
                                                     23
23
            A. Information about --
                                                                  A. Yes.
24
                MR. DAVIS: Objection to
                                                     2.4
                                                                     But if you see in that
                                     Page 551
                                                                                           Page 553
 1
            form
                                                       1
                                                              bullet point there, where it says,
                                                              Visiting faculty. Visiting faculty is
 2
                THE WITNESS: Information
                                                       2
 3
                                                       3
                                                              the promotional speakers bureau, that's
            about the therapeutic area,
            information about the risks,
 4
                                                       4
                                                              not independent education faculty.
 5
                                                       5
            information about the appropriate
                                                              Publications, again, that's not
 6
            assessment tools.
                                                       6
                                                              independent education. Phase IV is
                                                       7
 7
                As we said, that whole gamut
                                                              always a necessity, product specific.
 8
                                                       8
                                                              And advisory boards, again, do not fall
            of information is appropriate.
 9
        BY MS. AMINOLROAYA:
                                                       9
                                                              under the purview of independent
10
            Q. Right. And the output of
                                                     10
                                                              education
        that, at least based on what I see on
11
                                                     11
                                                                      So when we're talking about
12
        Page 5, is one, Competitive advantage for
                                                      12
                                                              advocates, that's the context of that,
                                                     13
13
        Endo.
                                                              and influentials, as opposed to
14
                Did I read that correctly?
                                                     14
                                                              therapeutic experts. So just to clarify
                                                      15
15
            A. Yes.
                                                              that.
16
            Q. And two is, Expanded use of
                                                     16
                                                                  Q. And if Endo could gain --
                                                     17
                                                              could win over these -- these therapeutic
17
        current and future products.
18
                Did I read that correctly?
                                                     18
                                                              experts and key opinion leaders, it would
                                                     19
                                                              give it the competitive advantage, right,
19
            A. Yes.
                                                     20
                                                              that you discussed here on Page 5 of this
20
                And I think I've made no --
21
                                                      21
        I've been very transparent about the fact
                                                              presentation, and also provide expanded
22
        that I think Endo is a company that has a
                                                     22
                                                              use of current and future products,
2.3
        competitive edge, advantage, in how they
                                                     23
                                                              correct?
                                                      24
24
        approach their -- their business, as
                                                                      MR. DAVIS: Objection to
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THE WITNESS: Certainly, if we had the if we had therapeutic experts who were knowledgeable about our data, who what the sudgested that would definitely be a competitive advisory boards and provide a greet hat when you were contential – the potential – the fact of the potential – the potential – the potential – the potential				
THE WITNESS: Certainly, if we had the if we had therapeutic experts who were knowledgeable about our data, who were knowledgeable about our the Phase IV studies and the additional research that we were additional research that were addition		Page 554		Page 556
THE WITNESS: Certainly, if we had the if we had thereapeutic experts who were knowledgeable about our data, who were knowledgeable about our the Phase IV studies and the additional research that we were additional research that were additio	1	form.	1	Kitlinski, because initiatives that
we had the — if we had therapeutic experts who were knowledgeable about our data, who were knowledgeable about our — the Phase IV studies and the additional research that we were planning, that would give us a competitive advantage.  Having them participate on competitive advantage.  Having them participate on definitely be a competitive advantage, ves.  MR. DAVIS: Objection to form.  HEWITNESS: No. As we — we had this discussion earlier when you asked that same question. As I mentioned, opiophobia is not the healthy respect and fear of the potential — the potential abuse, misuse, addiction, overdose aspects that are associated with opioids. H's the unwillingness to consider that as a — an that they suggested, that would definitely be a competitive definitely be a competitive advantage, ves.  MR. DAVIS: Objection to form.  Having them participate on definitely respect and fear of the potential — the potential abuse, misuse, addiction, overdose aspects that are associated with opioids. H's the unwillingness to consider that as a — an therapeutic option for patients. And also that if they don't utilize the medications appropriately, you could actually have the exact opposite effect of what you were just referring to a moment ago.  Page 555  Page 557  I line.  Did I read that correctly? MR. DAVIS: Objection to form.  Fage 557  I line.  Did I read that correctly? MR. DAVIS: Objection to form.  Fage 557  Page 557  Page 557  Page 557  Page 557  Page 557  A. Sure. Q. —you would agree that decorters had a fear of opioids in the wake of what was going on with Purdue and OxyContin?  MR. DAVIS: Objection to form.  THE WITNESS: Yes, that's development, not consistent with what the current form.  And, again, I don't want to keep reiterating this, but just to keep in mind the time frame here of 2000, you know, early in the company's development, not consistent with what the current R. DAVIS: Objection to form.  THE WITNESS: Yes, that's decorters had a fear of opioids in the wake of what was going on with Purdue and OxyContin			2	
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	Page 558		Page 560
1	the FDA.	1	family physicians, and other
2	BY MS. AMINOLROAYA:	2	primary care folks were critical
3	Q. And so you don't recall when	3	to the appropriate pain management
4 .	Purdue's problems with OxyContin first	4	and that they did not have
5	surfaced in the news?	5	education on that, short of one
6	MR. DAVIS: Objection to	6	hour during their during their
7	form.	7	training programs.
8	THE WITNESS: As I as I	8	BY MS. AMINOLROAYA:
9	stated, I recall that it was in	9	Q. And if we look at Exhibit-2,
10	the early 2000s. Without a frame	10	the CD&E objectives that we just
11	of reference to look back at, I	11	discussed for clinical development and
12	don't, I'm sorry.	12	education objectives at Endo, had the
13	BY MS. AMINOLROAYA:	13	objective of expanding use of current and
14		14	future products.
15	Q. You had a very good memory	15	
	during Mr. Davis's examination. I will		And that's not the only time
16	note that.	16	we saw that, Ms. Kitlinski. We also saw
17	A. Mr. Davis was examining me	17	that goal in Exhibit-2, for example.
18	about the aspects of my job relating to	18	Number 3 in your 1999 objectives stated,
19	educational specifics that I had written,	19	Maximize corporate return on current
20	the elements for that RiskMAP. So I have	20	product lines and seek support for new
21	a very clear recollection of that, as I	21	product initiatives, correct?
22	did for when you were asking me about	22	MR. DAVIS: Objection to
23	education-related things as well.	23	form.
24	Q. And yet another tactic on	24	THE WITNESS: Correct. And
	Dog 550		Dago 561
	Page 559		Page 561
1	Page 16 of the document is to establish	1	as we discussed, again, at this
2	pain management as a priority with PCPs.	2	time, in this early stage of the
3	And this was another tactic	3	company's development, the focus
4	towards the goal of gaining that CD&E	4	was not on independent education,
5	had in the year 2000 of sowing,	5	it was on as a company,
6	watering or, excuse me, hoeing,	6	everyone had your colleague
7	planting seeds and watering in order to	7	commented on the EBITDA term,
8	obtain growth in the opioids market,	8	which is certainly not one that I
9	correct?	9	would have grasped myself.
10	MR. DAVIS: Objection to	10	So there were certain
11	form.	11	initiatives that the entire
12	THE WITNESS: No. This was	12	company had to embrace as a new
13	referring to the fact that primary	13	startup company.
14	care physicians that the data	14	And, again, the education
15	was suggesting that primary care	15	that we're talking about here
16	physicians were responsible for	16	focused on educational
17	managing the great majority of	17	initiatives, working with the
18	patients with pain, especially as	18	professional organizations. And
19	the healthcare system evolved and	19	the patient organizations were
20	visits to specialists became more	20	not were not separate and apart
21	costly and less accessible for	21	from the responsibilities at that
22	patients.	22	time.
23	So it was recognizing that	23	BY MS. AMINOLROAYA:
24	internal medicine specialists,	24	Q. And this
2 7	memai medieme speciansis,		Q. Full tills

	Page 562		Page 564
1	A. So I believe may I just	1	Yes, the same again, once
2	ask never mind. It's probably not	2	again, what we just spoke to, in a
3	appropriate. I can't ask a question, I'm	3	young company like that, everyone
4 .	sorry.	4	was all hands on board bringing
5	Q. I'm sorry, it's not.	5	their their aspects to the
6	A. Okay.	6	table of what they can contribute
7	Q. And if we turn to	7	to the launch.
8	Exhibit-5 are you familiar with the	8	BY MS. AMINOLROAYA:
9	IMS data, Ms. Kitlinski?	9	Q. All right. And let's turn
10	MR. DAVIS: How about you	10	to Page 14 of Exhibit-5.
11	wait until she has the document?	11	And Page 14 here, it
12	THE WITNESS: I know what	12	states
13		13	
	IMS data is. I don't know,	14	A. Yes, I have it. I was just
14	like I don't see it.		looking back to see whose presentation
15 16	I understand that that's	15	this was. Okay. I got it.
16	how, for example, the FDA	16	Q. We looked at this earlier.
17	determined how many	17	This was, Endo Commercial Capabilities
18	extended-release, ER	18	Overview by Jeremy Goldberg. We
19	extended-release and long-acting	19	identified that the metadata for this
20	opioids were being prescribed at	20	document placed this document as a 2005
21	the time that they put the REMS in	21	document.
22	place and how many how many	22	A. Yes. And this particular
23	prescribers, I should say, not	23	slide, though, that you're talking about,
24	opioids, and that's how they	24	14, was not Jeremy Goldberg's. He was in
	- 3		
1	determined their goals for what	1	
1	determined their goals for what	1	the corporate development.
2	the REMS education should	2	the corporate development.  But it was, rather, Mark
2	the REMS education should encompass.	2 3	the corporate development.  But it was, rather, Mark Gossett, who was the senior vice
2 3 4	the REMS education should encompass.  So I'm familiar with what	2 3 4	the corporate development.  But it was, rather, Mark Gossett, who was the senior vice president of the commercial business.
2 3 4 5	the REMS education should encompass.  So I'm familiar with what IMS data is.	2 3 4 5	the corporate development.  But it was, rather, Mark Gossett, who was the senior vice president of the commercial business.  Q. Okay. Thank you.
2 3 4 5 6	the REMS education should encompass. So I'm familiar with what IMS data is. BY MS. AMINOLROAYA:	2 3 4 5 6	the corporate development.  But it was, rather, Mark Gossett, who was the senior vice president of the commercial business.  Q. Okay. Thank you. A. Sure.
2 3 4 5 6 7	the REMS education should encompass. So I'm familiar with what IMS data is. BY MS. AMINOLROAYA: Q. Thank you.	2 3 4 5 6 7	the corporate development.  But it was, rather, Mark Gossett, who was the senior vice president of the commercial business. Q. Okay. Thank you. A. Sure. Q. And Page 14, Endo describes
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	Page 566		Page 568
1	BY MS. AMINOLROAYA:	1	if that's correct or not. That's
2	Q. And does the second bullet	2	Mr. Gossett's representation of
3	under Percocet state, Endo grew from \$40	3	the data.
4 .	million to \$214 million by 2003?	4	BY MS. AMINOLROAYA:
5	A. That is what Mr. Gossett	5	Q. If this data is, in fact,
6	says on his slide, yes.	6	correct, this would mean that the
7	Q. And so the CD&E strategy to	7	withdrawn. Let's move on.
8	grow sales and grow the market for	8	Earlier you testified do
9	Percocet, it worked, Ms. Kitlinski,	9	you recall offering testimony about
10	correct?	10	ACCME?
11		11	A. ACCME?
	MR. DAVIS: Objection to	12	
12 13	form.	13	Q. Yes.
	THE WITNESS: The company's		A. Yes.
14	strategy to launch new forms of	14	Q. And you said that anyone
15	Percocet that were more	15	or separate from your testimony from
16	available I'm sorry, more	16	ACCME, but you said anyone can lodge a
17	appropriate, including, as we had	17	complaint to a CME-accrediting
18	talked earlier about Percolone,	18	organization.
19	which was did not have the	19	Do you recall that
20	acetaminophen component of that,	20	testimony?
21	that contributed towards this.	21	MR. DAVIS: Objection to
22	What the CD&E contribution	22	form.
23	was, I don't know how you would	23	THE WITNESS: Yes.
24	how you would gauge that.	24	BY MS. AMINOLROAYA:
	Page 567		Daga E60
			Page 569
1	BY MS. AMINOLROAYA:	1	Q. And did Endo ever lodge such
2	BY MS. AMINOLROAYA: Q. But the CD&E, as a member,	2	Q. And did Endo ever lodge such a complaint?
2	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this	2 3	Q. And did Endo ever lodge such
2 3 4	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right?	2 3 4	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.
2 3 4 5	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right? This was your objective, to	2 3 4 5	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did
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2 3 4 5 6	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right? This was your objective, to grow the market for Percocet?	2 3 4 5 6	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as
2 3 4 5 6 7	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right? This was your objective, to grow the market for Percocet? MR. DAVIS: Objection to	2 3 4 5 6 7	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as did your previous your
2 3 4 5 6 7 8	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right? This was your objective, to grow the market for Percocet? MR. DAVIS: Objection to form.	2 3 4 5 6 7 8	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as did your previous your colleague, and I indicated that I
2 3 4 5 6 7 8 9	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right? This was your objective, to grow the market for Percocet? MR. DAVIS: Objection to form. BY MS. AMINOLROAYA: Q. And six years later, we see	2 3 4 5 6 7 8	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as did your previous your colleague, and I indicated that I was not aware of that.  BY MS. AMINOLROAYA:
2 3 4 5 6 7 8 9	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right? This was your objective, to grow the market for Percocet? MR. DAVIS: Objection to form. BY MS. AMINOLROAYA: Q. And six years later, we see that Percocet sales quintupled, from \$40	2 3 4 5 6 7 8 9	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as did your previous your colleague, and I indicated that I was not aware of that.
2 3 4 5 6 7 8 9 10	BY MS. AMINOLROAYA: Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right? This was your objective, to grow the market for Percocet? MR. DAVIS: Objection to form. BY MS. AMINOLROAYA: Q. And six years later, we see that Percocet sales quintupled, from \$40 million to \$214 million I'm sorry, not	2 3 4 5 6 7 8 9 10	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as did your previous your colleague, and I indicated that I was not aware of that.  BY MS. AMINOLROAYA:  Q. Let's go to Exhibit-43.  Do you recall Mr. Davis
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MS. AMINOLROAYA:  Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right?  This was your objective, to grow the market for Percocet?  MR. DAVIS: Objection to form.  BY MS. AMINOLROAYA:  Q. And six years later, we see that Percocet sales quintupled, from \$40 million to \$214 million I'm sorry, not even six years later.  Four years later Percocet sales quintupled from \$40 million to \$214 million and Percocet becomes the gold standard in pain management.  Approximately 77 percent of prescriptions for Oxycodone with acetaminophen are written as Percocet; is that correct?  MR. DAVIS: Objection to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as did your previous your colleague, and I indicated that I was not aware of that.  BY MS. AMINOLROAYA:  Q. Let's go to Exhibit-43.  Do you recall Mr. Davis asking you some questions about responsible opioid prescribing?  MR. DAVIS: Let's wait until she has it in front of her, please.  BY MS. AMINOLROAYA:  Q. My question doesn't have to do with the document yet.  Do you recall the line of questioning?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MS. AMINOLROAYA:  Q. But the CD&E, as a member, you were the director of CD&E, and this was your strategy in 1999, right?  This was your objective, to grow the market for Percocet?  MR. DAVIS: Objection to form.  BY MS. AMINOLROAYA:  Q. And six years later, we see that Percocet sales quintupled, from \$40 million to \$214 million I'm sorry, not even six years later.  Four years later Percocet sales quintupled from \$40 million to \$214 million and Percocet becomes the gold standard in pain management.  Approximately 77 percent of prescriptions for Oxycodone with acetaminophen are written as Percocet; is that correct?  MR. DAVIS: Objection to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And did Endo ever lodge such a complaint?  MR. DAVIS: Objection to form.  THE WITNESS: No. You did ask me that question and I as did your previous your colleague, and I indicated that I was not aware of that.  BY MS. AMINOLROAYA:  Q. Let's go to Exhibit-43.  Do you recall Mr. Davis asking you some questions about responsible opioid prescribing?  MR. DAVIS: Let's wait until she has it in front of her, please.  BY MS. AMINOLROAYA:  Q. My question doesn't have to do with the document yet.  Do you recall the line of questioning?

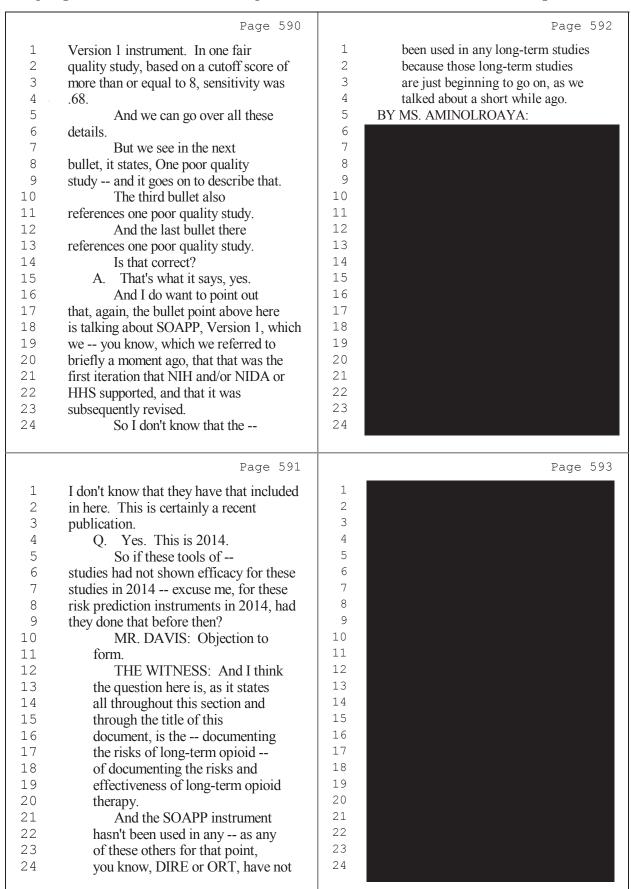
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Page 570
                                                                                              Page 572
 1
        you're referring to?
                                                         1
                                                                second edition by the APS.
            Q. Yes.
 2
                                                         2
                                                                        And this was Exhibit -- 12?
 3
            A. Yes.
                                                         3
                                                                That doesn't sound right.
 4
                                                         4
                                                                       MR. DAVIS: 42.
            Q. And I believe the concern in
                                                         5
 5
        this line of questioning was that not
                                                                BY MS. AMINOLROAYA:
        enough pages from the book were covered.
                                                         6
 6
 7
                And you may or may not know,
                                                         7
                                                                       So let's look at some of
 8
        Mrs. Kitlinski, we have limited time and
                                                         8
                                                                these pages.
        we have to move along. We only have
 9
                                                         9
                                                                    A. Sure.
10
                                                       10
                                                                    Q. Page 95. And under,
        seven hours.
                There's certainly more
                                                       11
                                                                Addiction, physical dependence and
11
        content in here that we could cover with
12
                                                       12
                                                                tolerance, if you look at the third
                                                                paragraph under that subheading, it
13
        you. And we can look at one more example
                                                       13
        to address your concern. It's here on
14
                                                       14
                                                                states, The prevalence of addiction among
15
        Page 36 of the document.
                                                                patients who do not have a previously
                                                       15
                                                                existing substance abuse disorder is low.
16
            A. 36 up --
                                                       16
            Q. Yes. 423.36.
                                                       17
                                                                       Did I read that correctly?
17
            A. -- the actual -- okay.
                                                       18
                                                                    A. Yes, you did.
18
19
            Q. And I'm only going to read
                                                       19
                                                                    Q. All right. And following
        the first sentence, for time and for all
                                                                that it says, Weissman and Haddox, 1989,
20
                                                       20
21
        of our sakes.
                                                       21
                                                                noted that patients who are given doses
22
            A. Sure.
                                                       22
                                                                of opioids that are inadequate to relieve
23
            Q. It says, Beware the
                                                       23
                                                                their pain or whose opioid dose is
24
        distinction between pseudoaddiction and
                                                       2.4
                                                                discontinued abruptly or tapered too
                                      Page 571
                                                                                              Page 573
 1
        addiction
                                                                rapidly may develop characteristics that
                                                         1
                                                                resemble addiction, which they termed
 2
            A. Yes. We brought that up in
                                                         2
 3
        the past discussion.
                                                         3
                                                                iatrogenic pseudoaddiction.
            Q. We actually covered more
                                                                       And the last sentence there
 4
                                                         4
        than one page --
                                                         5
                                                                states, Requests for these specific
 5
            A. Yes. And that's why I said
 6
                                                         6
                                                                medications and doses should not be
 7
        I wasn't sure how many pages, but --
                                                         7
                                                                interpreted as necessarily indicating
 8
            Q. Okay. You said we had not
                                                         8
                                                                drug-seeking behavior.
 9
        covered a lot of it, so I wanted to make
                                                         9
                                                                       Did I read that correctly?
10
        sure we give it some more attention.
                                                       10
                                                                    A. Yes. It was just the
11
            A. Absolutely.
                                                                intervening section -- sentence there
                                                       11
                And my concern was not so
12
                                                       12
                                                                that put it into context that, Because
        much the number of pages, but just an
13
                                                       13
                                                                patients are often knowledgeable about
14
        isolation -- you know, the focus on a
                                                       14
                                                                their medications and doses that have
        bullet point such as this as opposed to
                                                       15
                                                                worked in the past, requests for these
15
        the general gestalt of the book, which
                                                                medications and doses should not be
16
                                                       16
17
        was that addiction and abuse and misuse
                                                                interpreted as -- necessarily as
                                                       17
18
        and overdose are serious societal issues
                                                       18
                                                                drug-seeking behavior.
19
                                                       19
                                                                    Q. Right. And this paragraph
        that need to be addressed.
20
            Q. Another complaint that was
                                                       2.0
                                                                frames this in terms of pseudoaddiction,
21
        discussed during the examination was that
                                                       21
                                                                correct?
22
        we didn't look at particular pages in the
                                                       22
                                                                    A. Yes.
23
        2002 Guideline for the Management of Pain
                                                       2.3
                                                                    Q. And it relies on the
24
        and Osteoarthritis, Rheumatoid Arthritis,
                                                       24
                                                                Weissman and Haddox article from 1989,
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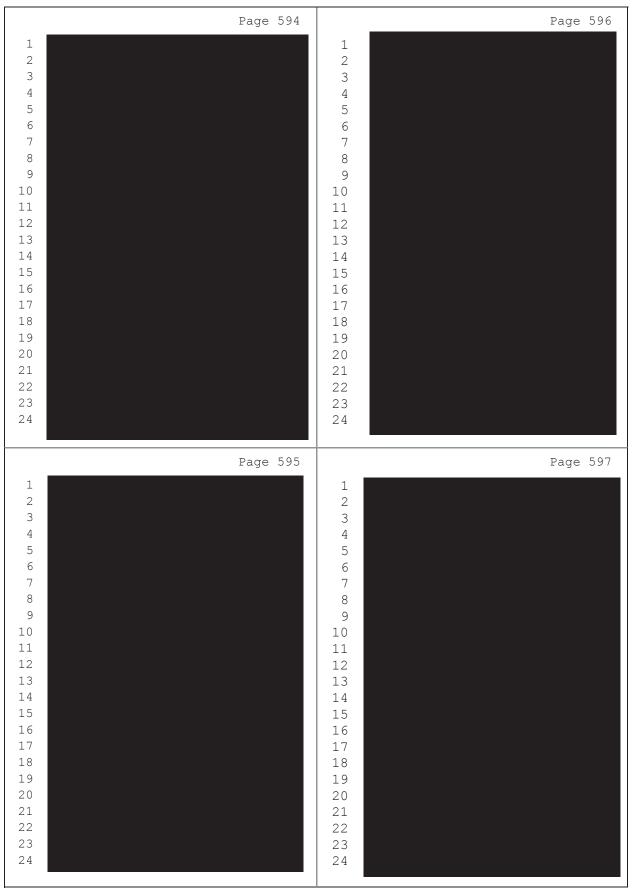
	Page 574		Page 576
1	correct?	1	A. AHRQ.
2	A. Correct.	2	Q. AHRQ, thank you.
3	MR. DAVIS: Objection to	3	And based on the evidence
4 .	form.	4	study that was prepared for that agency,
5	BY MS. AMINOLROAYA:	5	the document stated that long-term
6	Q. And if we go to Page 97 of	6	studies have not been conducted on the
7	the document, we see here, in the	7	efficacy of opioids, correct?
8	beginning of the third full paragraph	8	MR. DAVIS: Objection to
9	or we can go to the top paragraph here.	9	form.
10	It says, Furthermore,	10	THE WITNESS: That was
11	decades of clinical experience and	11	the again, it was a very
12	studies conducted in patients with	12	lengthy document, and we just
13	chronic malignant pain due to a variety	13	looked at a few select items. And
14	of causes have demonstrated clearly the	14	I'm not saying we should have
15	usefulness of opioids in the management	15	looked at the whole thing.
16	of a variety of chronic nonmalignant pain	16	But I did not read that full
17	types.	17	document, and so my comments on
18	Did I read that correctly?	18	that were just what I said, that
19	A. Yes.	19	because of the requirements that
20	Q. And we read earlier the	20	the FDA puts forth for chronic
21	evidence study stating that opioids have	21	opioids to be approved, that's
22	not been studied for longer than	22	what had been studied and that my
23	long-term efficacy studies have not been	23	colleagues in clinical
24	conducted for opioids, correct?	24	development, for example, could
	D		D
	Page 575		Page 577
-1	MD DAME OF: "	1	-
1	MR. DAVIS: Objection to	1	speak more appropriately to the
2	form.	2	speak more appropriately to the current the current studies
2 3	form. THE WITNESS: Are you	2 3	speak more appropriately to the current the current studies that are being conducted to
2 3 4	form.  THE WITNESS: Are you referring to here, where it says,	2 3 4	speak more appropriately to the current the current studies that are being conducted to address that question.
2 3 4 5	form.  THE WITNESS: Are you referring to here, where it says, There is some evidence of a	2 3 4 5	speak more appropriately to the current the current studies that are being conducted to address that question.  Because, indeed, it has been
2 3 4 5 6	form.  THE WITNESS: Are you referring to here, where it says, There is some evidence of a positive risk-to-benefit ratio in	2 3 4 5 6	speak more appropriately to the current the current studies that are being conducted to address that question.  Because, indeed, it has been raised that there is not only
2 3 4 5 6 7	form.  THE WITNESS: Are you referring to here, where it says, There is some evidence of a positive risk-to-benefit ratio in the use of certain opioids for	2 3 4 5 6 7	speak more appropriately to the current the current studies that are being conducted to address that question.  Because, indeed, it has been raised that there is not only insufficient long-term evidence
2 3 4 5 6 7 8	form.  THE WITNESS: Are you referring to here, where it says, There is some evidence of a positive risk-to-benefit ratio in the use of certain opioids for people with moderate to severe	2 3 4 5 6 7 8	speak more appropriately to the current the current studies that are being conducted to address that question.  Because, indeed, it has been raised that there is not only insufficient long-term evidence with regards to the benefits, but
2 3 4 5 6 7 8 9	form.  THE WITNESS: Are you referring to here, where it says, There is some evidence of a positive risk-to-benefit ratio in the use of certain opioids for people with moderate to severe pain?	2 3 4 5 6 7 8	speak more appropriately to the current the current studies that are being conducted to address that question.  Because, indeed, it has been raised that there is not only insufficient long-term evidence with regards to the benefits, but also the risks. And so both of
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	form.  THE WITNESS: Are you referring to here, where it says, There is some evidence of a positive risk-to-benefit ratio in the use of certain opioids for people with moderate to severe pain?  BY MS. AMINOLROAYA: Q. No. I'm referring to the sentence I just read.  Were you with me? A. No, I'm sorry. I was not. Q. Let's look back up at the top.  A. I read the I did follow you there at the top, and I said yes.  But then I thought you asked me about something else. Q. Yes. So I said earlier we	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	speak more appropriately to the current the current studies that are being conducted to address that question.  Because, indeed, it has been raised that there is not only insufficient long-term evidence with regards to the benefits, but also the risks. And so both of those are being pursued as we speak.  BY MS. AMINOLROAYA:  Q. And does FDA prevent a company like Endo from conducting a study on the long-term safety and efficacy of opioids?  MR. DAVIS: Objection to form.  THE WITNESS: No.  BY MS. AMINOLROAYA:  Q. Do any FDA regulations

	Page 578		Page 580
1	form.	1	BY MS. AMINOLROAYA:
2	THE WITNESS: I'm not the	2	Q. And here on Page 97, going
3	expert on regulatory issues or	3	down to the third paragraph, it states,
4 .	clinical development issues. So I	4	Evidence supports the use of Oxycodone
5	would suggest that you would raise	5	for moderate to severe pain that has not
6	that question with my colleagues.	6	responded to other treatments.
7	BY MS. AMINOLROAYA:	7	Is that correct?
8	Q. But you mentioned the FDA,	8	MR. DAVIS: Objection to
9	Ms. Kitlinski	9	form.
10	A. Yes.	10	THE WITNESS: Yes. And
11	Q correct?	11	that's the case for, again,
12	You said that the studies	12	positioning opioid, not opioids
13	were limited because of FDA, right?	13	not as a first-line agent, as I
14	A. No. I said the studies were	14	said when we spoke about this.
15	limited because that is the requirements	15	BY MS. AMINOLROAYA:
16	that the FDA has to obtain approval of a	16	Q. And Endo sold generic
17	new chronic	17	Oxycodone, correct?
18	Q. I think we're saying the	18	A. Endo had a several
19	same thing.	19	generic opioids and Oxycodone, I believe,
20	A. Okay. We are on the same	20	certainly, at one point in time we did.
21		21	I don't know if we still do.
22	page. Q. So there are certain studies	22	Q. And generic and Endo sold
23	that a company may conduct to obtain FDA	23	generic OxyContin after the publishing of
24	approval.	24	these guidelines in 2002, correct?
24	арргочаг.	24	these guidennes in 2002, correct?
	Page 579		Page 581
1	Does anything prevent a	1	MR. DAVIS: Objection to
2	company from conducting further studies?	2	form.
3	A. No.	3	THE WITNESS: I don't know
4	MD DAVIC. Objection to		
-	MR. DAVIS: Objection to	4	the answer to that question.
5	form.	4 5	the answer to that question. BY MS. AMINOLROAYA:
	5		-
5	form.	5	BY MS. AMINOLROAYA:
5 6 7 8	form. THE WITNESS: As is what	5 6	BY MS. AMINOLROAYA: Q. Okay. A. Because OxyContin was a different formulation than this is
5 6 7 8 9	form. THE WITNESS: As is what Endo is doing. BY MS. AMINOLROAYA: Q. And Endo had not	5 6 7 8 9	BY MS. AMINOLROAYA: Q. Okay. A. Because OxyContin was a different formulation than this is just saying generic Oxycodone, which is
5 6 7 8 9 10	form. THE WITNESS: As is what Endo is doing. BY MS. AMINOLROAYA:	5 6 7 8	BY MS. AMINOLROAYA: Q. Okay. A. Because OxyContin was a different formulation than this is just saying generic Oxycodone, which is the active ingredient, for example, in
5 6 7 8 9	form. THE WITNESS: As is what Endo is doing. BY MS. AMINOLROAYA: Q. And Endo had not	5 6 7 8 9	BY MS. AMINOLROAYA: Q. Okay. A. Because OxyContin was a different formulation than this is just saying generic Oxycodone, which is the active ingredient, for example, in Percocet. It's not an extended-release
5 6 7 8 9 10	form.  THE WITNESS: As is what Endo is doing.  BY MS. AMINOLROAYA: Q. And Endo had not conducted has not conducted those	5 6 7 8 9 10 11 12	BY MS. AMINOLROAYA: Q. Okay. A. Because OxyContin was a different formulation than this is just saying generic Oxycodone, which is the active ingredient, for example, in Percocet. It's not an extended-release formulation of that.
5 6 7 8 9 10 11	form.  THE WITNESS: As is what Endo is doing.  BY MS. AMINOLROAYA: Q. And Endo had not conducted has not conducted those studies in the past, correct?	5 6 7 8 9 10 11	BY MS. AMINOLROAYA: Q. Okay. A. Because OxyContin was a different formulation than this is just saying generic Oxycodone, which is the active ingredient, for example, in Percocet. It's not an extended-release
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5 6 7 8 9 10 11 12 13 14 15 16	form.  THE WITNESS: As is what Endo is doing.  BY MS. AMINOLROAYA: Q. And Endo had not conducted has not conducted those studies in the past, correct?  MR. DAVIS: Objection to form.  THE WITNESS: They have conducted longer studies, but these are long you know, longer	5 6 7 8 9 10 11 12 13 14 15 16	BY MS. AMINOLROAYA: Q. Okay. A. Because OxyContin was a different formulation than this is just saying generic Oxycodone, which is the active ingredient, for example, in Percocet. It's not an extended-release formulation of that. Q. Right. And you discussed some of your significant responsibilities with the RiskMAP. Do you recall there being a
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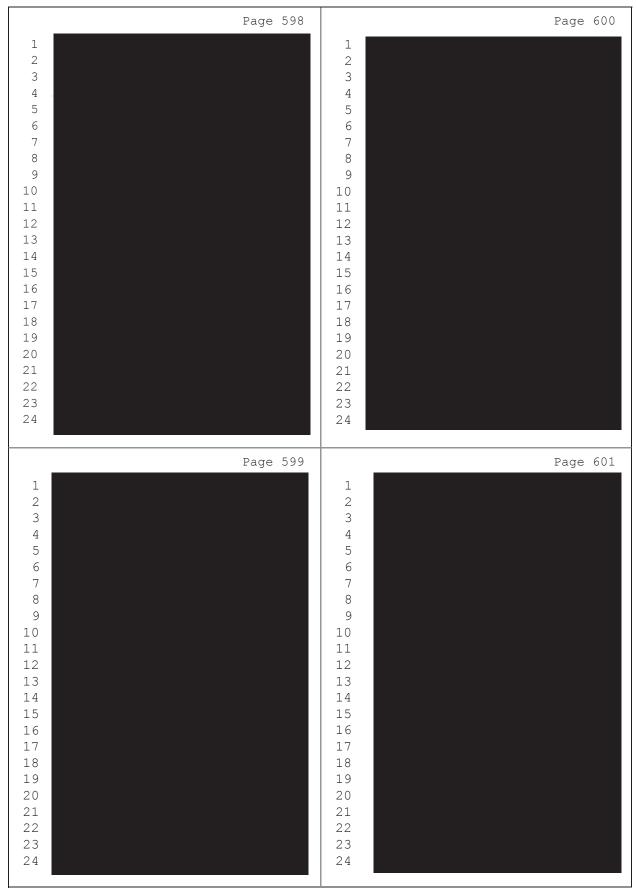
1 2 3	Page 582		Page 584
	know.	1	in one of these slides. It's a
3	BY MS. AMINOLROAYA:	2	self-administered form excuse me, it's
	Q. So you recall the RiskMAP	3	a fourteen-item self-administered form
4 .	for Opana ER, but you don't recall the	4	capturing the primary determinants of
5	RiskMAP for generic OxyContin?	5	aberrant drug-related behavior.
6	A. The RiskMAP for	6	Did I read that correctly?
7	MR. DAVIS: Object to form.	7	A. I'm sorry, I was assisting
8	THE WITNESS: The RiskMAP	8	to locate an item.
9	for generic I'm sorry, for	9	A fourteen-item
10	Opana ER was negotiated and put in	10	self-administered form capturing the
11	place with the FDA while I was	11	primary determinants of aberrant
12	responsible for that. So, yes, I	12	drug-related behavior, yes.
13	definitely recall that. I was	13	Q. And this was something that
14	involved in it.	14	was that Endo suggested to doctors
15	BY MS. AMINOLROAYA:	15	could be used to manage the risks of
		16	
16 17	Q. You don't recall a RiskMAP	17	addiction, correct?  MR. DAVIS: Objection to
	for generic Oxycodone or generic		3
18	OxyContin?	18	form.
19	MR. DAVIS: Objection to	19	THE WITNESS: The SOAPP tool
20	form.	20	was the if you recall earlier,
21	THE WITNESS: As I said, I	21	we talked about psychometrically
22	don't even recall if we sold that	22	validated tools that were
23	drug.	23	supported by funding from NIDA or
24	BY MS. AMINOLROAYA:	24	from NIH, and that Endo also
	Page 583		Page 585
1	Q. Convenient.	1	provided some educational grant
2	A. No. Just the fact that the	2	support towards.
3	generic formulations change, literally,	3	So this was a tool that was
4	from month to month and year to year, and	4	developed and I don't recall if
5	that was quite a number of years ago.	5	it was NIDA or NIH, but it was
6	Q. And another let's turn	6	funding from them. And then Endo
7	back to Exhibit-40.	7	provided educational additional
8	Another complaint that was	8	educational grants so that the
9	lodged about our review of the APS	9	beta the beta version of it,
10	residents course was also that we didn't	10	once they received the feedback
11	cover enough pages here.	11	from clinicians as to what would
12	Turning to Page 34 of the	12	work in their practice on a
13	document, the second slide on this page	13	day-to-day basis, they were able
14	mentions, Screener and opioid assessment	14	to modify that so it could be
15	for patients in pain, or SOAPP.	15	practical and inserted into their
16	You're familiar with SOAPP,	16	patient care.
	Ms. Kitlinski?	17	BY MS. AMINOLROAYA:
17		18	
17	A. Yes.		Q. And I think my question was,
18	Q. And this relates to opioids,	19	SOAPP was something that Endo suggested
18 19	1.40		
18 19 20	right?	20	to doctors could be used to manage the
18 19 20 21	So this addresses your	21	risks of addiction; is that right?
18 19 20 21 22	So this addresses your concern that we weren't addressing slides	21 22	risks of addiction; is that right?  MR. DAVIS: Objection to
18 19 20 21	So this addresses your	21	risks of addiction; is that right?

	Page 586		Page 588
1	of the independent educational	1	Q. And the key point is, No
2	activities. And so this is	2	study evaluated the effectiveness of risk
3	this is not Endo suggesting SOAPP,	3	prediction instruments for reducing
4 .	this is the APS residents course.	4	outcomes related to overdose, addiction,
5			
6	It's not that Endo did not,	5	abuse or misuse. SOE: Insufficient.
	you know, speak to the value of	6	Did I read that correctly?
7	SOAPP. I didn't mean to imply	7	A. Yes.
8	that. But I just want to be clear	8	And I just wanted to see
9	that this was the faculty for the	9	what this citation here, 113 and 14 is
10	program.	10	that they're citing, because it seems at
11	And we did, indeed and we	11	odds with the fact that they're saying
12	did, indeed, recognize the value	12	there was no study, and yet they have a
13	of SOAPP, because the FDA, NIH and	13	citation.
14	NIDA had acknowledged its	14	So just give me one moment
15	importance by virtue of the fact	15	to look what they
16	that they supported ongoing	16	Q. Well, we can look at
17	research with it and utilized it	17	let's look at Question 4A on Page 86.
18	as one of the tools that they	18	A. Okay.
19	when they were conducting their	19	Q. Key Question 4A is, In
20	evaluations.	20	patients with chronic pain being
21	BY MS. AMINOLROAYA:	21	considered
22	Q. When did FDA support	22	A. Excuse me just one second
23	research of SOAPP?	23	here. I'm just trying to get to that
24	A. FDA did not. NIDA or NIH	24	page.
	Page 587		Page 589
1	_	1	_
1 2	did, yes.	1 2	46, you said?
2	did, yes. Q. And SOAPP was part of the	2	46, you said? 4A, okay. I have it.
2 3	did, yes. Q. And SOAPP was part of the RiskMAP for Opana ER, correct?	2 3	46, you said? 4A, okay. I have it. That's on Page 41.
2 3 4	did, yes. Q. And SOAPP was part of the RiskMAP for Opana ER, correct? A. Yes.	2 3 4	46, you said? 4A, okay. I have it. That's on Page 41. Q. In patients with chronic
2 3 4 5	did, yes. Q. And SOAPP was part of the RiskMAP for Opana ER, correct? A. Yes. Q. However, when the evidence	2 3 4 5	46, you said? 4A, okay. I have it. That's on Page 41. Q. In patients with chronic pain being considered for long-term
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2 3 4 5 6 7	did, yes. Q. And SOAPP was part of the RiskMAP for Opana ER, correct? A. Yes. Q. However, when the evidence report was prepared for AHRQ if you turn to Exhibit-24.	2 3 4 5 6 7	46, you said? 4A, okay. I have it. That's on Page 41. Q. In patients with chronic pain being considered for long-term opioid therapy, what is the accuracy of instruments for predicting risk of opioid
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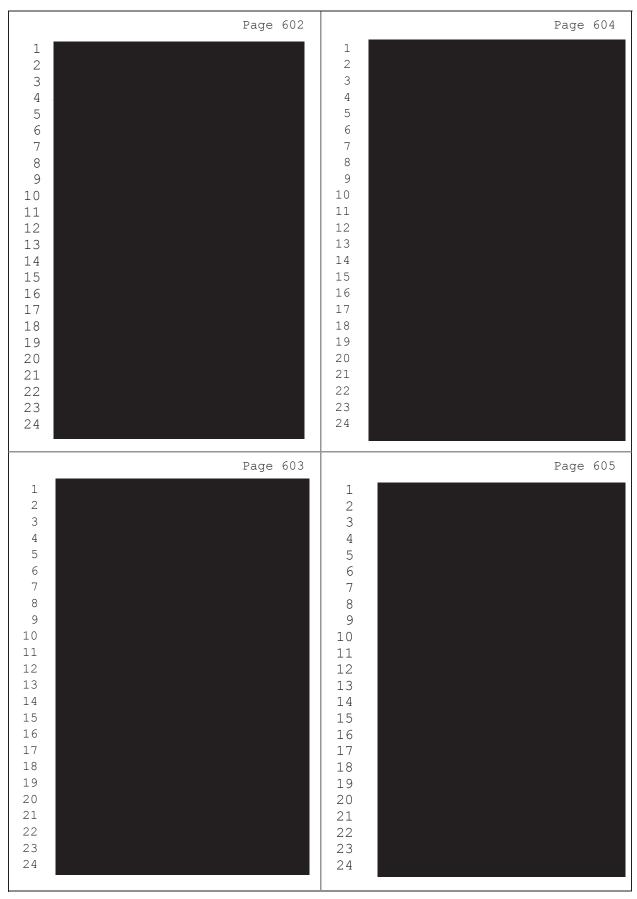




150 (Pages 594 to 597)

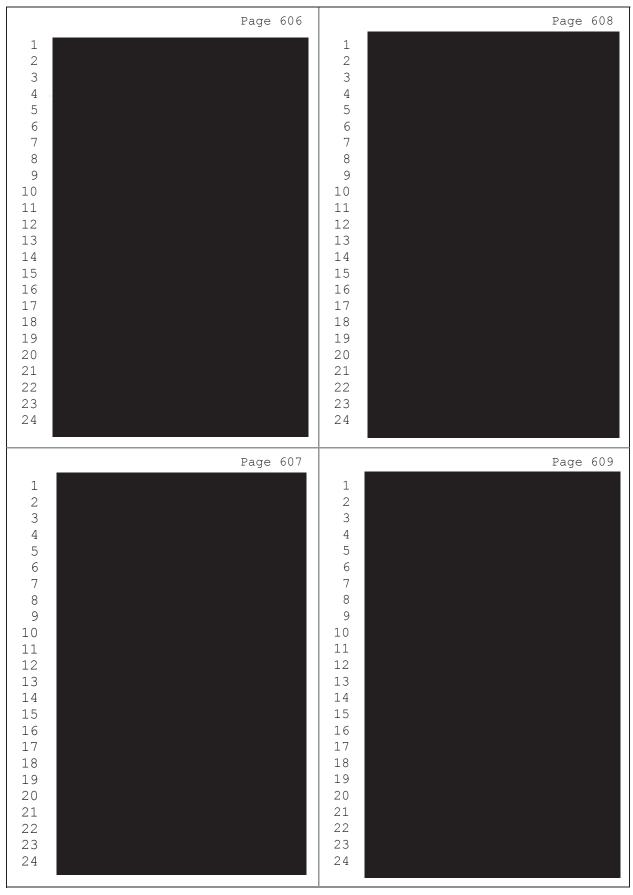


151 (Pages 598 to 601)

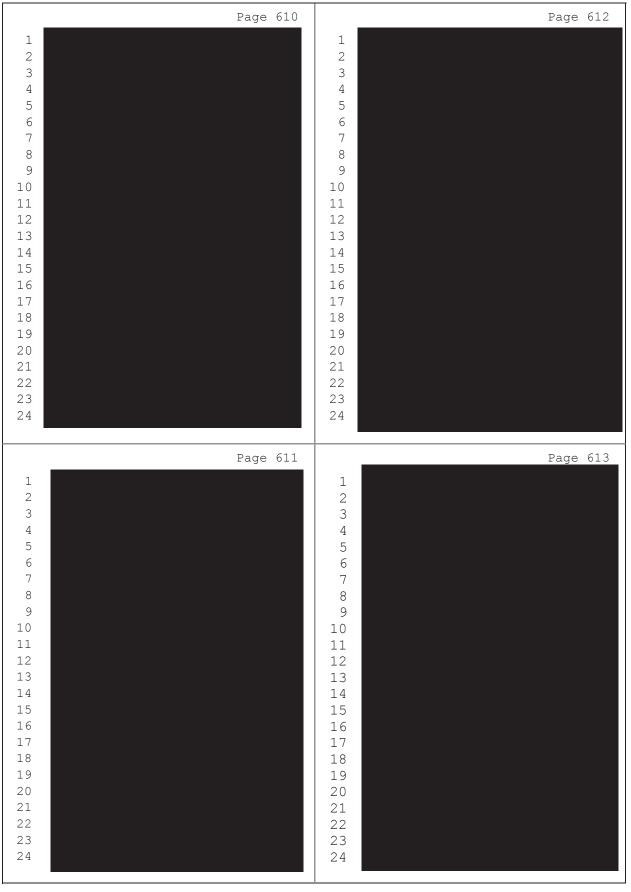


152 (Pages 602 to 605)

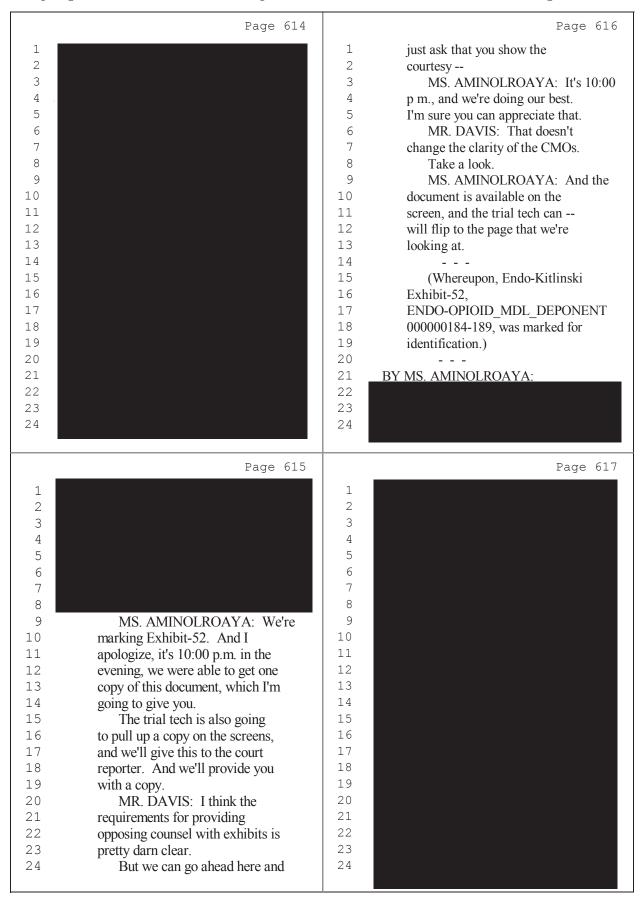
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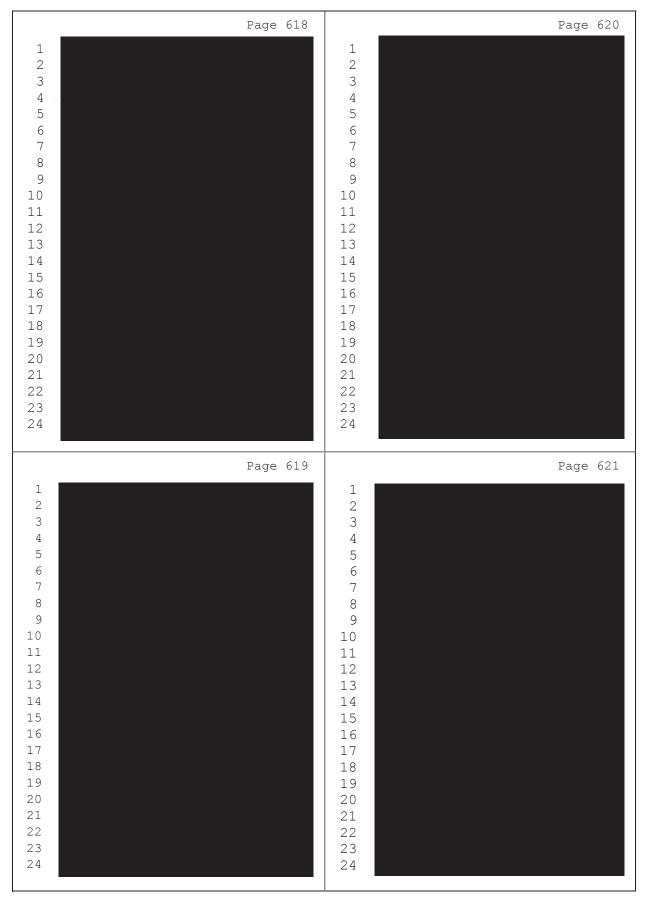
153 (Pages 606 to 609)



154 (Pages 610 to 613)



155 (Pages 614 to 617)



156 (Pages 618 to 621)

	Page 622		Page 624
1		1	CERTIFICATE
2		2	
3		3	
4	MR. DAVIS: Objection to the	4	I HEREBY CERTIFY that the
5	form. That's all the time we	5	witness was duly sworn by me and that the
6	have.	6	deposition is a true record of the
7	MS. AMINOLROAYA: How much	7	testimony given by the witness.
		8	
8	time do I have left?	9	
9	VIDEO TECHNICIAN: That was	10	
10	one hour		Amanda Maslynsky-Miller
11	MR. DAVIS: Okay. You're	11	Certified Realtime Reporter
12	done.		Dated: January 16, 2018
13	MS. AMINOLROAYA: I just	12	
14	have one more question with this,	13	
15	if counsel would indulge me.	14	
16	MR. DAVIS: We gave Dave	15	
17	five extra minutes	16	(TT) 0
18	MS. AMINOLROAYA: I just	17	(The foregoing certification
19	have literally one more	18	of this transcript does not apply to any
20	question	19	reproduction of the same by any means,
21	MR. DAVIS: You're done.	20	unless under the direct control and/or
22	MS. AMINOLROAYA: that	21	supervision of the certifying reporter.)
23	will take 60 seconds.	22	
23	MR. DAVIS: Thank you.	23 24	
24	MR. DAVIS. Thank you.	24	
	Page 623		Page 625
1	MS. AMINOLROAYA: It will	1	INSTRUCTIONS TO WITNESS
2	take 60 seconds.	2	INSTRUCTIONS TO WITHLISS
3	MR. DAVIS: We're off the		
		1 3	Please read vour denosition
Λ		3	Please read your deposition
4	record. We're done.	4	over carefully and make any necessary
5	record. We're done. VIDEO TECHNICIAN: This ends	4 5	over carefully and make any necessary corrections. You should state the reason
5 6	record. We're done. VIDEO TECHNICIAN: This ends today's deposition. We're going	4 5 6	over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata
5 6 7	record. We're done. VIDEO TECHNICIAN: This ends	4 5 6 7	over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.
5 6 7 8	record. We're done.  VIDEO TECHNICIAN: This ends today's deposition. We're going off the record at 10:04 p.m.	4 5 6 7 8	over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.  After doing so, please sign
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